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EASTERN DISTRICT OF WASHINGTON

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**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON**

UNITED STATES OF AMERICA ex
rel. UPPI, LLC,

Plaintiff-Relator,

v.

CARDINAL HEALTH, INC.;
CARDINAL HEALTH 414, LLC d/b/a
CARDINAL HEALTH NUCLEAR
PHARMACY SERVICES; CARDINAL
HEALTH 200, LLC; D'S VENTURES
LLC d/b/a LOGMET SOLUTIONS,
LLC; CARING HANDS HEALTH
EQUIPMENT & SUPPLIES, LLC;
OTHER UNNAMED SMALL
BUSINESS FRONT COMPANIES,
OBIE B. BACON, and DEMAURICE
SCOTT, and UNNAMED
INDIVIDUALS (DOES)

Defendants.

No. **2:17-CV-378-RMP**
[SEALED]
**COMPLAINT PURSUANT TO
31 U.S.C. § 3730**

[DEMAND FOR JURY TRIAL]

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COMPLAINT

COMES NOW, UPPI, LLC (“UPPI” or “Relator”), through the undersigned attorneys, on behalf of the United States of America, and files this *qui tam* Complaint against Defendants Cardinal Health, Inc. and its related entities (“Cardinal Health”), Caring Hands Health Equipment & Supplies LLC (“Caring Hands”), D’s Ventures LLC d/b/a Logmet Solutions LLC (“Logmet”), Obie B. Bacon, DeMaurice Scott, and unnamed individuals (“Does”) (collectively “Defendants”), and alleges as follows:

I. INTRODUCTION

1. Since at least 2013, Defendants conspired to fraudulently obtain government contracts involving highly dangerous and sensitive radiopharmaceutical products. A radiopharmaceutical can be used for either diagnostic or therapeutic purposes. Radioactive materials are regularly used to treat medical conditions, diagnosis pathology, and visualize and measure physiological functions. Specifically, Defendants caused contracts to be awarded to SDVOSB “front companies” that were unlicensed and unqualified to handle these dangerous products that were administered to people. In doing so, they abused government programs designed to help disabled veterans and encourage small business development.

2. In a nutshell, Fortune 500 company Cardinal Health (large publicly-

1 traded company) paired with one or more small businesses, including Caring
2 Hands and Logmet, in the solicitation and ultimate award of highly specialized
3 contracts for the manufacture and distribution of radiopharmaceutical products.
4 Cardinal Health had an interest in becoming affiliated with these small business
5 partners because of their status as "Service-Disabled Veteran-Owned Small
6 Businesses" ("SDVOSBs") to gain an unfair and illegal advantage in obtaining
7 government contracts that it would otherwise not have been entitled or able to
8 obtain. Put another way, these SDVOSB partners were the "front companies" for
9 Cardinal Health. Cardinal Health was so confident in this scheme that it engaged
10 in these type of fraudulent arrangements with multiple small businesses.
11
12
13

14 3. The government contracts were supposed to be awarded by the United
15 States Department of Veterans Affairs ("VA") to businesses that could
16 manufacture, market and distribute nuclear pharmaceuticals, a highly-specialized
17 and highly-regulated practice area. That's what Congress wanted. In several
18 instances, the contracts were explicit small business set asides for SDVOSBs. In
19 other instances, the contracting officers or officials responsible for the award and
20 administration of these contracts sought to award unrestricted contracts to
21 SDVOSBs to meet contracting quotas. In either instance, Cardinal Health
22 improperly used the SDVOSB partner to gain an advantage in the bid solicitation
23 process.
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28 4. The purpose behind the Service-Disabled Veteran-Owned Small

1 Business (“SDVOSB”) program is obvious. Such businesses are supposed to be
2 exactly what their name suggests—service-disabled-veteran owned. In this case,
3 the small business and the big company fraudulently gained an unfair advantage
4 over other smaller businesses, contrary to what Congress intended. The small
5 businesses (Caring Hands and Logmet) did not have the expertise, qualifications or
6 certifications required to provide the highly-specialized services. Only the
7 company worth billions (Cardinal Health) had the expertise to perform the work
8 under the contract. The entire venture between the front companies and Cardinal
9 Health was a sham to obtain radiopharmaceutical product contracts generally, and
10 further to seek and obtain set aside contracts intended to help small nuclear
11 pharmacies.
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16 5. Both Cardinal Health and the front companies gained financially from
17 the scheme. Cardinal Health paid the front companies kickbacks in the form of a
18 percentage mark-up on the contracts, and Cardinal Health effectively “won” the
19 contracts as a behind the curtain subcontractor or partner, pocketing the remaining
20 contract award and performing a majority of the work.
21
22

23 6. In furtherance of this scheme, Defendants also misrepresented their
24 capabilities of furnishing low energy uranium (“LEU”) radiopharmaceutical
25 products required by the VA contracts, and instead disbursed high energy uranium
26 (“HEU”) radiopharmaceutical products. Cardinal Health has been awarded over
27 \$300 million in radiopharmacy contracts with the VA since 2013. These
28

1 companies lied and conspired to get the contracts from the VA. This fraudulent
2 scheme and conspiracy is ongoing.

3
4 7. Cardinal Health and its front companies conspired for financial gain in
5 violation of the False Claims Act. Other small specialty pharmacies, for which the
6 small business designations were intended to support, naturally were harmed by
7 this conspiracy.
8

9 8. As the U.S. Small Business Administration (“SBA”) states:

10 Small businesses have always been the engine for
11 economic growth. They provide jobs, innovation and
12 bring competition to the marketplace. The Government’s
13 procurement policy – which encourages “maximum
14 practicable” prime and subcontracting opportunities for
15 small businesses – is a catalyst for economic growth.
16 With a government contracting market representing more
17 than a half trillion dollars, it makes solid economic sense
18 to help small firms get their fair share of federal contract
19 dollars.

20 U.S. Small Business Administration, Office of Government Contracting &
21 Business Development, “Government Contracting 101, Part 1 – Small Business
22 Contracting Programs: A Guide for Small Business,” at 6 (January 2012),
23 [https://www.sba.gov/sites/default/files/files/Work%20book%20gc%20101%20part](https://www.sba.gov/sites/default/files/files/Work%20book%20gc%20101%20part%201.pdf)
24 [%201.pdf](https://www.sba.gov/sites/default/files/files/Work%20book%20gc%20101%20part%201.pdf).

25 9. As the SBA further states, “[s]mall business set-asides are a powerful
26 tool for helping small businesses compete for and win federal contracts. . . . When
27 market research concludes that small businesses are available and able to perform
28

1 the work or provide the products being procured by the government, those
2 opportunities are 'set-aside' exclusively for small business concerns." U.S. Small
3 Business Administration, "What is a Small Business Set-Aside?"
4 [https://www.sba.gov/contracting/government-contracting-programs/what-small-](https://www.sba.gov/contracting/government-contracting-programs/what-small-business-set-aside)
5 [business-set-aside.](https://www.sba.gov/contracting/government-contracting-programs/what-small-business-set-aside)
6

7 8 **II. LEGAL FRAMEWORK**

9 **A. Parties.**

10 10. Relator UPPI is a membership organization and limited liability
11 company, organized under the laws of the State of Delaware, and having at all
12 times relevant to this action, its principal place of business in Suwanee, Georgia.
13 UPPI promotes the business interests and manages the growth of its approximately
14 eighty-seven (87) members, which are individual, small business, and university-
15 based nuclear pharmacies engaged in the manufacturing, production, marketing,
16 sales, and distribution of nuclear pharmaceuticals, including positron emission
17 tomography ("PET") radiopharmaceuticals. UPPI is an organization dedicated to
18 advancing the professionalism of the nuclear and PET pharmacy industries.
19

20 11. Defendant Cardinal Health 414, LLC d/b/a Cardinal Health Nuclear
21 Pharmacy Services, is a limited liability company organized under the laws of the
22 State of Delaware, with its principal place of business in Dublin, Ohio, and is a
23 wholly-owned subsidiary of Cardinal Health Inc. Cardinal Health 414
24
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1 “manufactures, dispenses and delivers radiopharmaceuticals with expert efficiency
2 to the highest regulatory standards.”
3

4 12. Defendant Cardinal Health 200 is a limited liability company
5 organized under the laws of the State of Delaware, with its principal place of
6 business in Dublin, Ohio, and is a wholly-owned subsidiary of Cardinal Health,
7 Inc. that engages in the marketing of pharmaceutical preparations and medical
8 equipment, instruments, and supplies.
9

10 13. Defendant Cardinal Health, Inc., is a Top 15 Fortune 500 publicly-
11 traded company, which also has its principal place of business in Dublin, Ohio.
12 Defendant Cardinal Health is engaged in providing healthcare products to
13 pharmacies, hospitals, and ambulatory care sites, including cold chain-refrigerated
14 pharmaceutical tote packaging for pharmacy deliveries, franchise pharmacies,
15 nuclear pharmacy services, specialty pharmaceutical distribution, and specialty
16 pharmaceutical services. On its website, Cardinal Health represents itself as
17 follows: “Headquartered in Dublin, Ohio, Cardinal Health, Inc. (NYSE: CAH) is a
18 global, integrated healthcare services and products company, providing customized
19 solutions for hospital systems, pharmacies, ambulatory surgery centers, clinical
20 laboratories and physician offices worldwide;” as a “\$103 billion health care
21 services company that improves the cost-effectiveness of health care.” Its Chief
22 Executive Officer is George S. Barrett. Cardinal Health may be served with
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1 process through its registered agent for service of process, CT Corporation System,
2 1300 East Ninth Street, Cleveland, Ohio 44114.
3

4 14. Cardinal Health and all its related-entities named in this Complaint are
5 referred to collectively as “Cardinal Health.”
6

7 15. Defendant Caring Hands Health Equipment & Supplies, LLC
8 (“Caring Hands”) is a limited liability company, organized under the laws of the
9 State of South Carolina, and having at all times relevant to this action, its principal
10 place of business in Ridgeland, South Carolina. Caring Hands represents on its
11 website that it is engaged in providing home healthcare services, supplying durable
12 medical equipment (“DME”) and government contracting. The company, through
13 its owner and CEO, Obie B. Bacon, is certified as a SDVOSB, a Veteran Owned
14 Small Business, and a Minority-Owned Small Business by the Small Business
15 Administration. Caring Hands may be served with process through its registered
16 agent for service of process, Obie B. Bacon, 61 Riverwalk Boulevard, Unit C,
17 Ridgeland, South Carolina 29936.
18
19
20

21 16. Obie B. Bacon is the Chief Executive Officer and owner of Caring
22 Hands, together with his spouse, and formed the organization in 2009.
23

24 17. Defendant D’s Ventures, LLC d/b/a Logmet Solutions, LLC
25 (“Logmet”) is a limited liability company, organized under the laws of the State of
26 Georgia, and having at all times relevant to this action, its principal place of
27 business in McDonough, Georgia. Logmet represents on its website that it
28

1 “provides one-stop single source purchasing for all your medical and dental
2 products and supplies at competitive prices [offering] over 300,000 healthcare and
3 dental manufacturer products.” The company, through its owner and CEO,
4 DeMaurice Scott, is certified as a SDVOSB, a Veteran Owned Small Business, and
5 a Minority-Owned Small Business by the Small Business Administration. Logmet
6 may be served with process through its registered agent for service of process,
7 DeMaurice Scott, 301 Little Gem Ct, McDonough, GA 30253.

10 18. DeMaurice Scott is the Chief Executive Officer and owner of Logmet.

12 19. Other unnamed individuals (Does) may include contracting officers or
13 other individuals who conspired to, or participated in the fraudulent scheme set
14 forth in this Complaint, in violation of the False Claims Act.

16 **B. Jurisdiction and Venue.**

17 20. This Court has subject matter jurisdiction over the claims asserted
18 herein pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and 28 U.S.C.
19 § 1331.

21 21. Venue is proper in this judicial district pursuant to 31 U.S.C. §
22 3732(a) because one or more defendants may be found, resides, and/or transacts
23 business in this District, or because an act, proscribed by 31 U.S.C. § 3729,
24 occurred in this District.
25
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1 **C. The Applicable Laws.**

2 **1. The Federal False Claims Act**

3
4 22. The False Claims Act provides, in part: Liability for Certain Acts.—

5 (1) In general.—[] any person who— (A) knowingly presents, or causes to be
6 presented, a false or fraudulent claim for payment or approval; (B) knowingly
7 makes, uses, or causes to be made or used, a false record or statement material to a
8 false or fraudulent claim; [] (G) knowingly makes, uses, or causes to be made or
9 used, a false record or statement material to an obligation to pay or transmit money
10 or property to the Government, or knowingly conceals or knowingly and
11 improperly avoids or decreases an obligation to pay or transmit money or property
12 to the Government, [] is liable to the United States Government for a civil penalty
13 of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil
14 Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–
15 410 [1]), plus 3 times the amount of damages which the Government sustains
16 because of the act of that person. 31 U.S.C. § 3729(a)(1)(A), (B), (G).

17
18
19
20
21 23. Under the False Claims Act, scienter must be demonstrated:

22 **Definitions—**

23
24 For purposes of this section— (1) the terms “knowing” and “knowingly”— (A)
25 mean that a person, with respect to information— (i) has actual knowledge of the
26 information; (ii) acts in deliberate ignorance of the truth or falsity of the
27 information; or (iii) acts in reckless disregard of the truth or falsity of the
28

1 information; and (B) require no proof of specific intent to defraud; (2) **the term**
2 **“claim”** — (A) means any request or demand, whether under a contract or
3 otherwise, for money or property and whether or not the United States has title to
4 the money or property, that— (i) is presented to an officer, employee, or agent of
5 the United States; or (ii) is made to a contractor, grantee, or other recipient, if the
6 money or property is to be spent or used on the Government’s behalf or to advance
7 a Government program or interest, and if the United States Government— (I)
8 provides or has provided any portion of the money or property requested or
9 demanded; or (II) will reimburse such contractor, grantee, or other recipient for
10 any portion of the money or property which is requested or demanded; [] . 31
11 U.S.C. § 3729(b)(1)-(2).
12
13
14
15

16 **2. The Anti-Kickback Statute**

17 **24.** The Anti-Kickback Statute provides additional causes of action: (b)
18 **Illegal remunerations**—(1) Whoever knowingly and willfully solicits or receives
19 any remuneration (including any kickback, bribe, or rebate) directly or indirectly,
20 overtly or covertly, in cash or in kind— (A) in return for referring an individual to
21 a person for the furnishing or arranging for the furnishing of any item or service for
22 which payment may be made in whole or in part under a Federal health care
23 program, or (B) in return for purchasing, leasing, ordering, or arranging for or
24 recommending purchasing, leasing, or ordering any good, facility, service, or item
25 for which payment may be made in whole or in part under a Federal health care
26
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1 program, shall be guilty of a felony and upon conviction thereof, shall be fined not
2 more than \$25,000 or imprisoned for not more than five years, or both. (2)
3
4 Whoever knowingly and willfully offers or pays any remuneration (including any
5 kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in
6 kind to any person to induce such person— (A) to refer an individual to a person
7 for the furnishing or arranging for the furnishing of any item or service for which
8 payment may be made in whole or in part under a Federal health care program, or
9 (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or
10 ordering any good, facility, service, or item for which payment may be made in
11 whole or in part under a Federal health care program, shall be guilty of a felony
12 and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned
13 for not more than five years, or both. 42 U.S.C. § 1320a-7b(b).

17 25. (h) **Actual knowledge or specific intent not required**—With
18 respect to violations of this section, a person need not have actual knowledge of
19 this section or specific intent to commit a violation of this section. 42 U.S.C.
20 §1320a-7b(h).

22 **D. Applicable Laws Aimed at Helping Small Businesses**

23
24 26. The federal government created a government contracting program
25 known as the “small business set aside” to help small businesses compete for
26 federal government purchases that amount in hundreds of billions of dollars for
27 goods and services.
28

1 27. The U.S. Small Business Administration states that “[w]hen market
2 research concludes that small businesses are available and able to perform the
3 work or provide the products being procured by the government, those
4 opportunities are ‘set-aside’ exclusively for small business concerns.” U.S. Small
5 Business Administration Website, “What is a Small Business Set Aside?”
6 [https://www.sba.gov/contracting/government-contracting-programs/what-small-](https://www.sba.gov/contracting/government-contracting-programs/what-small-business-set-aside)
7 [business-set-aside.](https://www.sba.gov/contracting/government-contracting-programs/what-small-business-set-aside)
8
9

10 28. Small business set asides are further refined into specific categories,
11 including 8(a) business development programs, Women-Owned Small Businesses,
12 Service-Disabled Veteran-Owned Businesses, and Small Mentor-Protégé
13 Programs. 13 C.F.R. §§ 124.1 – 124.704 (8(a) business), 125.9 (mentor-protégé
14 program), 125.11 – 125.33 (service disabled veteran), 127.100 – 701 (women-
15 owned small business).
16
17

18 29. These sub-categories of small business are identified, in part, as 8(a)
19 small business development, women-owned small business (“WOSB”), and
20 service-disabled veteran-owned small business programs (“SDVOSB”). *See id.*
21
22

23 30. The 8(a)-small business development program is intended to help
24 small, disadvantaged businesses including economically disadvantaged businesses
25 and socially disadvantaged businesses (or minority owned businesses). 13 C.F.R.
26 §§ 124.1, 124.101.
27
28

1 31. The SDVOSB program is intended to allow federal agencies exclusive
2 set asides for SDVOSBs and sole source awards to SDVOSBs if certain conditions
3 are met. 13 C.F.R. §§ 125.8 – 125.10.
4

5 32. As of the date of the enactment of the SBA in 1958, Congress
6 required at least 23 percent of all federal government contracting dollars to be
7 awarded to small businesses. 15 U.S.C.A. § 644 (g)(1)(A)(i).
8

9 33. Since then, the federal government further stipulated that of that 23
10 percent, at least 5 percent must be awarded to small disadvantaged businesses and
11 at least 3 percent must be awarded to service disabled veteran owned small
12 businesses. 15 U.S.C.A. § 644 (g)(1)(A)(ii), (iv).
13

14 34. The quota mandates became even more specific when the SBA
15 established a process for negotiating and establishing agency specific quotas for
16 each of these categories. 15 U.S.C.A. § 644 (g).
17

18 35. For fiscal year 2017, the VA is required to award 28.5% of its
19 contracts to prime small businesses and of that amount, at least five percent must
20 be awarded to 8(a) disadvantaged businesses and three percent to SDVOSBs. May
21 25, 2017 Memorandum from Secretary of Veterans Affairs concerning Fiscal Year
22 (FY) 2017 Department of Veterans Affairs (VA) Socioeconomic Procurement
23 Goals.
24
25
26
27
28

1 36. When small businesses are awarded set-aside contracts in excess of
2 \$150,000, the small business is required to perform at least 50 percent or more of
3 the work.
4

5 37. Accordingly, the small business should be acting as the prime if the
6 small business engages a subcontractor to perform some of the work. 13 C.F.R. §
7 125.6.
8

9 38. Specifically, for service contracts, the small business prime contractor
10 must provide at least 50 percent of the contract cost for personnel.
11

12 39. On supply contracts, the small business prime must perform work for
13 at least 50 percent of the cost of manufacturing the supplies, not including the cost
14 of the materials, unless the small business prime qualifies as a non-manufacturer.
15 13 C.F.R. § 125.6(a)(1) – (a)(2).
16

17 40. The non-manufacturer rule provides for small businesses to supply
18 products that it did not manufacture by engaging in a subcontract pairing with
19 another business.
20

21 41. But the non-manufacturer rule still requires the subcontracting of
22 work to another small business.
23

24 42. More specifically, the specific criteria require that (1) the products
25 must come from another domestic small business; and (2) the small business must
26 take ownership and possession of the furnished items with its own personnel,
27
28

1 equipment or facilities, before the products are provided to the government agency.

2 13 C.F.R. § 125.6(a)(2).

3
4 43. In short, a small business cannot subcontract 50% or more of the work
5 to another entity unless that entity is another small business.

6 44. The only exception to this rule is if the SBA issues a waiver. 13
7 C.F.R. §§ 121.406(b)(5), 125.6(a)(2).

8
9 45. There are two types of waivers that can be issued – class waivers or
10 individual waivers. Those waivers cannot even be considered until after extensive
11 market research and support that there is no small business manufacturer within the
12 industry or individually who can meet the requirement of a specific contract
13 solicitation. 13 C.F.R. §§ 121.406(b)(6), 121.1204.

14
15 46. Based on information and belief, the SBA has not issued a class
16 waiver for manufacturers of radiopharmaceutical products, and the SBA has not
17 provided Cardinal Health with an individual waiver in the manufacture or
18 distribution of radiopharmaceutical products.

19
20 47. Subcontracting on small business contracts is permissible if small
21 businesses adhere to the 50 percent thresholds, i.e., less than 50 percent of the
22 work is subcontracted to another entity.

23
24 48. When subcontracting, prime small businesses are not required to
25 represent to the agency who awarded the contract that they are subcontracting
26
27
28

1 services pursuant to the contract, provided that they meet the aforementioned
2 mandates. 13 C.F.R. § 125.3(b)(2); 13 C.F.R. § 121.404(g)(3)(ii).

3
4 49. Specifically, prime small businesses are not asked to submit a formal
5 subcontracting plan but are only “encouraged to provide maximum practicable
6 opportunity to other small businesses to participate in the performance of the
7 contract.” 13 C.F.R. § 125.3(b)(2).

8
9 50. Instead, it is only when specifically requested by the contracting
10 officer when a small business prime may be required to submit a subcontracting
11 plan, and only then if the contracting officer suspects a change in the contractor’s
12 status from small to other than small. 13 C.F.R. § 121.404(g)(3)(ii).

13
14 **E. Applicable Laws Aimed at Helping Veterans**

15
16 51. According to the third annual interagency Task Force on Veterans
17 Small Business Development (Task Force) report, sent to President Barack Obama
18 on October 16, 2015 (“the Task Force Report”), the United States has a strong
19 interest in supporting veterans who want to start or acquire a business.

20
21 52. Congress’ sweeping enactment of legislation in roughly the last
22 decade has been aimed at bolstering the economic need of veterans and veteran-
23 owned small businesses including service-disabled veteran-owned small
24 businesses.

25
26 53. In supporting veterans and veteran-owned small businesses, the
27 federal government is supporting the health of the United States economy.
28

1 54. Congress enacted legislation with the view that the three main
2 business development areas that veterans and veteran-owned small businesses need
3 are: (1) access to technical assistance, including management assistance; (2) access
4 to capital; and (3) access to federal contracting.
5

6 55. In short, Congress had as its goal the empowerment of veterans
7 through entrepreneurship.
8

9 56. Congress recognized that veterans have been and continue to be vital
10 to small business enterprises of the United States.
11

12 57. The Task Force Report further explained that Congress determined
13 that the United States has not done enough to assist veterans, particularly service-
14 disabled veterans, in greater participation in the U.S. economy.
15

16 58. Congress recognized that the nation must provide additional
17 assistance and support to veterans who have taken great risks to serve our country.
18

19 59. In response, Congress passed three pieces of legislation since 1999 to
20 address concerns about the inadequacy of services to veterans and service-disabled
21 veterans who either own or wish to start a small business, as set forth below.
22

23 **1. The Veterans Entrepreneurship and Small Business**
24 **Development Act of 1999**

25 60. The Veterans Entrepreneurship and Small Business Development Act
26 of 1999 (Public Law 106-50) expanded existing assistance and established new
27 assistance for veterans who own or operate small businesses. It also made
28

1 provisions for general business loan programs, for assistance to active-duty
2 military reservists, for creating disaster loan assistance to military reservists, and
3 for the addition of veterans in a smaller-loan program.
4

5 61. In the area of federal procurement, the 1999 law established an annual
6 Government-wide goal that at least three (3) percent of the total value of all prime
7 contract and subcontract awards be awarded to small businesses that are owned
8 and controlled by service-disabled veterans. 15 U.S.C. § 644(g).
9

10 62. In short, the 1999 law provided this assistance to veterans and service-
11 disabled veterans:
12

13 a) Technical assistance: SCORE program, entrepreneurship
14 assistance, business development and management assistance for
15 military reservists' small businesses
16

17 b) Financial assistance: General business loan programs,
18 assistance to active-duty military reservists, microloan program
19

20 c) Procurement assistance: subcontracting goal for participation in
21 federal procurement
22

23 **2. The Veterans Benefit Act of 2003**

24 63. The Veterans Benefit Act of 2003 (Public Law 108-183) provided
25 further assistance to veterans. It gave veterans access to entrepreneur training and
26 further allowed limiting competition to SDVOSBs for federal contracts. This Act,
27 under Title III, provided for the following:
28

1 a) Section 305 authorized state agencies to approve certain non-
2 degree, non-credit entrepreneurship courses enabling or assisting
3 veterans to start or enhance a small business.
4

5 b) Section 308 amended the Small Business Act (15 U.S.C. 631, *et*
6 *seq.*) establishing restricted competition and sole source authority on
7 federal contracts for small businesses owned and controlled by
8 service-disabled veterans.
9

10 c) It specifically added a contracting mechanism to enable
11 agencies to meet the three percent (3%) contracting goal. 15 U.S.C. §
12 657f. The Act permits a contracting officer to award a contract on a
13 sole source basis to any small business concern owned and controlled
14 by a service disabled veteran if: (1) the concern is determined to be a
15 responsible contractor with respect to performance of such contract
16 opportunity and the contracting officer does not have a reasonable
17 expectation that two (2) or more small business concerns owned and
18 controlled by service-disabled veterans will submit offers for the
19 contracting opportunity; (2) the anticipated award price of the contract
20 (including options) will not exceed — (A) \$5,000,000, in the case of a
21 contract opportunity assigned a standard industrial classification code
22 for manufacturing; or (B) \$3,000,000, in the case of any other
23 contract opportunity; and (3) in the estimation of the contracting
24
25
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27
28

1 officer, the contract award can be made at a fair and reasonable price.
2
3 15 U.S.C. § 657f(a). These restricted competitive procurements are
4 referred to as Government "Set-Asides."

5 **3. The Military Reservist and Veteran Small Business**
6 **Reauthorization and Opportunity Act Of 2008**

7 64. The Military Reservist and Veteran Small Business Reauthorization
8 and Opportunity Act of 2008 (Public Law 110-186) further expanded veterans'
9 small business opportunities. It provided the following:
10

- 11 a) Established the Interagency Task Force on Veterans Small
12 Business Development.
13
14 b) Authorized the permanent extension of SBA Advisory
15 Committee on Veterans Business Affairs established by Public Law
16 106-50.
17
18 c) Increased the number of Veterans Business Outreach Centers.
19
20 d) Authorized provisions for Reservist Programs.

21 **F. Requirements to Obtain Certification as A SDVOSB**

22 65. As indicated, the SDVOSB procurement program allows federal
23 agencies to set acquisitions aside for exclusive competition among SDVOSB
24 concerns.
25

26 66. To be certified as a SDOVSB and, thus, to become eligible to bid on
27 SDVOSB Set-Aside contracts, an entity must meet the following criteria:
28

- 1 a) The Service Disabled Veteran must have a service-connected
2 disability that has been determined by the Department of Veterans
3 Affairs or Department of Defense, 15 U.S.C. § 632(q);
4
5 b) The SDVOSB must be “small” under the North American
6 Industry Classification System (NAICS) code assigned to the
7 procurement;¹
8
9 c) The Service Disabled Veteran must unconditionally own 51%
10 of the SDVOSB;
11
12 d) The Service Disabled Veteran must control the management
13 and daily operations of the SDVOSB; and
14

15 ¹ The U.S. Small Business Administration (“SBA”) uses the North American
16 Industry Classification Systems (“NAICS”) as a basis for its size standards. When
17 the Federal government intends to acquire goods or services, it identifies the
18 NAICS code that describes the principal purpose of that procurement. The NAICS
19 classifies business establishments for the purpose of collecting, analyzing, and
20 publishing statistical data related to the U.S. economy. The NAICS industry codes
21 define establishments based on the activities in which they are primarily engaged.
22 NAICS codes are also used for administrative, contracting, and tax purposes.
23 NAICS is production oriented (not product oriented) and categorizes businesses
24 with others that have similar methods of production.
25
26
27
28

1 e) The Service Disabled Veteran must hold the highest officer
2 position in the SDVOSB.
3

4 67. The SDOVSB must also comply with certain limits on subcontracting
5 set forth at 13 C.F.R. § 125.6 (pre-June 30, 2016 Amendment):
6

7 a) In the case of a contract for services, the SDVOSB must
8 perform at least fifty (50) percent of the cost of the contract incurred
9 for personnel with its own employees; or
10

11 b) In the case of a contract for supplies, perform at least fifty (50)
12 percent of the cost of manufacturing the supplies or products, not
13 including the cost of materials.
14

15 68. As of June 30, 2016, a SDVOSB awarded a contract under the “Small
16 Business Set Aside” Program also must comply with the new Limitations on
17 Subcontracting Rule (“LOS”), 13 C.F.R. § 125.6(a), which requires that:
18

19 a) In the case of a contract for services (except construction), the
20 SDVOSB may not pay more than fifty (50) percent of the amount paid
21 to it by the Government to a subcontractor that is not similarly
22 situated. 13 C.F.R. § 125.6(a)(1).
23

24 b) In the case of a contract for supplies (other than from a non-
25 manufacturer of such supplies), the SDVOSB may not pay more than
26 fifty (50) percent of the amount paid to it by the Government to a
27 subcontractor that is not similarly situated. Costs of materials are
28

1 excluded and not considered to be subcontracted. 13 C.F.R. §
2 125.6(a)(2)(i).
3

4 69. A similarly situated entity is a subcontractor with the same “small
5 business program status as the prime contractor.”

6 70. Thus, for a SDVOSB prime contractor, a similarly situated
7 subcontractor is a self-certified SDVOSB.
8

9 71. In addition to sharing the same small business program status as the
10 prime contractor, a similarly situated entity must be small pursuant to the NAICS
11 code that the prime contractor assigned to the subcontract that the subcontractor
12 will perform. 13 C.F.R. § 125.1.
13

14 72. In the case of a contract for supplies valued at more than \$25,000,
15 where the SDVOSB is not the manufacturer of such supplies or performs less than
16 fifty (50) percent of the cost of manufacturing the supplies, the SDVOSB may
17 perform under the contract only if the SDVOSB partners with another U.S. based
18 company, which is “small” under the applicable NAICS code. 13 C.F.R.
19 §125.6(b)(4).
20
21

22 73. If a subcontractor performs the “primary and vital requirements” of a
23 contract, the contractor and subcontractor will be treated together as a joint-
24 venture.
25

26 74. If, however, the prime contractor is unduly reliant on the
27 subcontractor, the two businesses can no longer be classified as “small” under the
28

1 applicable NAICS code and the SDVOSB may not continue to certify as “small”
2 for that contract or for any task order under that contract. 13 C.F.R. §
3 121.103(h)(3).
4

5 75. Companies that are contracting as SDVOSBs must be registered as a
6 SDVOSB, and must certify to their SDVOSB status, whenever they submit a bid,
7
8 proposal, application or offer for a Federal grant, contract, subcontract, cooperative
9 agreement, or cooperative research and development agreement reserved, set aside,
10 or otherwise classified as intended for award to SDVO SBCs, as follows:
11

12 (1) Submission of a bid, proposal, application or offer
13 for a Federal grant, contract, subcontract, cooperative
14 agreement, or cooperative research and development
15 agreement reserved, set aside, or otherwise classified as
intended for award to SDVO SBCs.

16 (2) Submission of a bid, proposal, application or offer for
17 a Federal grant, contract, subcontract, cooperative
18 agreement or cooperative research and development
19 agreement which in any way encourages a Federal
20 agency to classify the bid or proposal, if awarded, as an
award to a SDVO SBC.

21 (3) Registration on any Federal electronic database for
22 the purpose of being considered for award of a Federal
23 grant, contract, subcontract, cooperative agreement, or
24 cooperative research and development agreement, as a
SDVO SBC.

25 13 C.F.R. § 121.108.

26 76. These regulations, representations, and certifications described in the
27 preceding paragraphs are material to the Government’s decisions to award
28

1 contracts and to pay the claims submitted under the contracts pursuant to the
2 Government Set-Asides awarded.

3
4 **1. The Rule of Two: The Supreme Court Kingdomware**
5 **Decision**

6
7 77. The Supreme Court recently decided a case concerning the award of
8 contracts to SDVOSBs, clarifying and otherwise upholding a specific component
9 of the Veterans Benefits, Health Care, and Information Technology Act of 2006,
10 38 U. S. C. §§8127, 8128, known as the “Rule of Two.” *Kingdomware*
11 *Technologies, Inc. v. United States*, 136 S. Ct. 1969, 1976 - 77 (2016).

13 78. As previously stated, Congress enacted the Veterans Benefits, Health
14 Care, and Information Technology Act of 2006 to set more specific annual goals
15 that encourage contracting with veteran-owned and service disabled veteran-owned
16 small businesses. 38 U.S.C. § 8127(a).

18
19 79. The Act required that “a contracting officer of the Department [of
20 Veterans Affairs] shall award contracts on the basis of competition restricted to
21 small business concerns owned and controlled by veterans if the contracting officer
22 has a reasonable expectation that two or more small business concerns owned and
23 controlled by veterans will submit offers and that the award can be made at a fair
24 and reasonable price that offers best value to the United States.” 38 U.S.C. §
25
26 8127(d) (emphasis added). This mandate has become known as the “Rule of
27
28 Two.”

1 80. Congress further provided for veteran owned business by further
2 restricting competition to veteran owned businesses with two exceptions.

3
4 81. Under these two exceptions, the VA may use noncompetitive and
5 sole-source contracts when the contracts are below specific dollar amounts.

6
7 82. Under §8127(b), the first exception provides that a contracting officer
8 “may use procedures other than competitive procedures” to award contracts to
9 veteran-owned small businesses when the goods or services that are the subject of
10 such contracts are worth less than the simplified acquisition threshold (also known
11 as “SAP awards”). 38 U. S. C. §8127(b)(emphasis added); 41 U. S. C. §134
12 (establishing a “simplified acquisition threshold” of \$100,000); see also §1908
13 (authorizing adjustments for inflation); 75 Fed. Reg. 53130 (codified at 48 CFR
14 §2.101 (2010)) (raising the amount to \$150,000).
15
16

17 83. Under 38 U. S. C. §8127(c), the second exception provides that a
18 contracting officer “may award a contract to a [veteran-owned small business]
19 using procedures other than competitive procedures” if the contract is worth more
20 than the simplified acquisition threshold but less than \$5 million, [and] the
21 contracting officer determines that the business is “a responsible source with
22 respect to performance of such contract opportunity,” and the award can be made
23 at “a fair and reasonable price.” 38 U. S. C. §8127(c) (emphasis added).
24
25
26

27 84. Kingdomware Technologies, Inc. was a service-disabled veteran-
28 owned small business that challenged the VA’s decision to award a contract to a

1 non-veteran owned company without restricting competition using the “Rule of
2 Two,” as required in 31 U.S.C. § 8127. *Kingdomware*, 136 S. Ct. at 1974 – 75.

3
4 85. The Rule of Two requires that the VA cannot award a contract
5 “without first checking to see whether at least two veteran-owned small businesses
6 could perform the work at a fair and reasonable price.” *Kingdomware*, 136 S. Ct.
7 at 1975.

8
9 86. The Court concluded that “§ 8127 unambiguously requires the
10 Department to use the Rule of Two before contracting under the competitive
11 procedures [requiring that] ‘a contracting officer of the Department [Veterans
12 Administration] *shall* award contracts’ to veteran-owned small businesses using
13 restricted competition *whenever the Rule of Two is satisfied*.” *Kingdomware*, 136
14 S. Ct. at 1976-77 (emphasis added).

15
16
17 87. Satisfaction of the Rule of Two requires that “the contracting officer
18 has a reasonable expectation that two or more small business concerns owned and
19 controlled by veterans [can and] will submit offers,” based on market research and
20 due diligence that two or more-small veteran owned businesses can act on the
21 contract. 38 U.S.C. § 8127(d).

22
23
24 88. The Court explained that “[t]he GAO issued a nonbinding
25 determination that the Department’s failure to employ the Rule of Two was
26 unlawful and recommended that the Department conduct market research to
27

1 determine whether there were two veteran-owned businesses that could fulfill the
2 procurement.” *Kingdomware*, 136 S. Ct. at 1975.

3
4 89. The Court further stated that “[o]n the merits, we hold that §8127 is
5 mandatory, not discretionary. Its text requires the Department to apply the Rule of
6 Two to all contracting determinations and to award contracts to veteran-owned
7 small businesses. The Act does not allow the Department to evade the Rule of Two
8 on the ground that it has already met its contracting goals or on the ground that the
9 Department has placed an order through the FSS.” *Kingdomware*, 136 S. Ct. at
10 1976 (emphasis added).
11
12

13 **2. Fraud on the VA is Given Heightened Attention in the**
14 **Current Administration –It’s a Top Priority for**
15 **Enforcement**

16 90. On May 2, 2017, President Trump issued Executive Order 13,793,
17 entitled “Improving Accountability and Whistleblower Protection at the
18 Department of Veterans Affairs.” Executive Order 13, 793, Volume 82, No. 83,
19 Part II (May 2, 2017).
20

21 91. The Order recognized that the VA needed additional support in
22 ferreting out problems at the VA with employees, contracting officers and
23 managers “who ha[d] violated the public’s trust and failed to carry out his or her
24 duties on behalf of veterans.”
25
26
27
28

1 92. The Order created a new office within the VA to assist the VA
2 Secretary in encouraging and resolving whistleblower complaints about
3 wrongdoing at the VA without fear of retaliation or other adverse action.
4

5 93. The Order recognized that there are problems within the VA
6 concerning wrongdoing that may undermine the very purpose of the agency and
7 the public's trust in its support and oversight of veterans' affairs.
8

9 94. The Order mandates that the VA, in conjunction with this
10 whistleblower office, "work closely with relevant VA components to ensure
11 adequate investigation and correction of wrongdoing," and "ensure swift and
12 effective resolution" of complaints.
13

14 95. Those concerns can be similarly voiced here in certain
15 contracting officials' conduct (or lack thereof) when evaluating the propriety
16 and capability of the defendant SDVOSBs' solicitations for these highly
17 specialized radiopharmaceutical contracts.
18
19

20 **III. ALLEGED FRAUDULENT SCHEME**

21 **A. Summary.**

22 96. UPPI brings this action on behalf of the United States of America
23 against Defendants to recover damages and civil penalties as a result of
24 Defendants' violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the
25 "FCA").
26
27
28

1 97. Specifically, Defendants defrauded the United States by engaging in
2 arrangements in which Small Businesses (“SBs”) and/or SDVOSBs would bid on,
3 and win Government contracts as prime contractors when such contracts were
4 designated as “Small Business Set-Asides” or otherwise awarded preferentially,
5 based on the owner’s status as a small business and a veteran. These contracts
6 primarily included, *inter alia*, contracts awarded by the VA for nuclear
7 pharmaceuticals, which these prime small businesses (“PSMs”), including Caring
8 Hands and Logmet, did not perform, and, in fact, could not have performed.
9

10
11
12 98. Instead, Cardinal Health, doing business as Cardinal Health Nuclear
13 Pharmacy Services, and these PSMs entered into agreements whereby these
14 contracts would largely, if not entirely, be performed by Cardinal Health.
15

16 99. Contrary to the SBA’s intent that small businesses perform at least 50
17 percent of the work, 13 C.F.R. § 125.6, in these arrangements, the small business
18 prime contractors (or front companies) performed or are performing a *de minimis*
19 amount of work because they cannot satisfy the contract requirements for
20 radiopharmaceutical products or services.
21

22 100. Neither Caring Hands, nor Logmet, have the necessary licensure,
23 personnel, facilities, equipment, or skill to provide radiopharmaceutical products or
24 services to VA pharmacies.
25

26 101. Instead, these front companies have to pair with Fortune 500
27 companies like Cardinal Health to perform on these radiopharmaceutical contracts.
28

1 102. Pairing or partnering on small business set aside contracts is not
2 categorically prohibited but there are clear specifications on how it can be done.
3
4 *E.g.*, 13 C.F.R. §§ 125.8, 125.18(b).

5 103. The SBA is clear that in both service and supply contracts, “the small
6 business prime contractor must provide at least 50% of the contract cost for
7 personnel” or “perform work for at least 50% of the cost of manufacturing the
8 supplies, not including the cost of materials.” U.S. Small Business Administration,
9 “What is a Small Business Set-Aside: Subcontracting Limitations; *see also* 13
10 C.F.R. § 125.6(a)(1) – (a)(2).
11
12

13 104. In the event that the small business prime does not itself manufacture
14 the product, the product must still only be supplied by another small business. U.S.
15 Small Business Administration, “What is a Small Business Set-Aside:
16 Subcontracting Limitations”; *see also* 13 C.F.R. § 125.6(a)(1) – (a)(2).
17
18

19 105. The size of a business – whether it is considered “small” pursuant to
20 SBA regulations – is determined by the NAICs code affiliated with that line of
21 business. 13 C.F.R. § 121.201.
22

23 106. NAICs stands for North American Industry Classification System and
24 is the standard used by the federal government in classifying business
25 establishments.
26

27 107. These VA contract solicitations use the NAICs code 325412, which is
28 defined as pharmaceutical preparation manufacturing. 13 C.F.R. § 121.201.

1 108. The SBA has established a threshold of the number of employees that
2 a small business soliciting contracts for pharmaceutical preparation manufacturing
3 with NAICS code 325412 must not exceed, which is 1,250. 13 C.F.R. § 121.201.
4

5 109. Cardinal Health 414, LLC has 3,000 employees and Cardinal Health,
6 Inc. has 37,300 employees.
7

8 110. Neither qualify as “small businesses” for contracts with NAICS code
9 325412.
10

11 111. Cardinal Health, which is a Top 25 Fortune 500 company and not a
12 SM or SDVOSB, defrauded the United States by using these PSMs to obtain these
13 radiopharmaceutical contracts under false and fraudulent pretenses, while
14 concealing or causing to be concealed its role in performing the contracts.
15

16 112. In exchange for using its SM and SDVOSB status to bid on and win
17 contracts under the “Small Business Set Aside” Program, these PSMs retained an
18 agreed upon percentage of the proceeds that was characterized as “overhead.”
19

20 113. In exchange for performing the contracts that it was barred from
21 obtaining and performing, and concealing that it had obtained and performed the
22 contracts by fraud, Cardinal Health received the rest of the proceeds.
23

24 114. At all times, Defendants knew that the contracts fraudulently awarded
25 to these PSMs, based, in part on their SM and SDVOSB status, would not be
26 performed in accordance with the Veterans Benefit Act of 2003 and the “Small
27 Business Set Aside” Program.
28

1 115. Defendants knowingly made, used, and caused to be made or used,
2 false records and statements material to false and fraudulent claims for payment, in
3 that, *inter alia*, Caring Hands and Logmet falsely certified and Cardinal Health
4 caused to be falsely certified, that Caring Hands and Logmet could and would
5 perform the contracts, and, in particular, that Caring Hands and Logmet were
6 licensed to perform the contracts, in violation of 31 U.S.C. § 3729(a)(1)(B).
7

8 116. Defendants further conspired to submit and caused to be submitted
9 false claims, and to make, use and cause to be made and used false records and
10 statements material to false and fraudulent claims, *to wit*, that Caring Hands and
11 Logmet had performed the contracts as required by and in compliance with the
12 “Small Business Set Aside” Program and federal regulations, in violation of 31
13 U.S.C. § 3729(a)(1)(C).
14

15 117. Individuals and businesses that seek to do business with the United
16 States must be honest and forthright in their dealings with the United States. The
17 same is true for individuals and businesses that apply for federal contracts,
18 particularly those contracts that are set aside to benefit veterans. The United States
19 should especially safeguard programs aimed at benefitting Small Businesses and
20 Service-Disabled Veteran-Owned Small Businesses.
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B. Unlike Caring Hands and Logmet, Nuclear Pharmacies Are Highly Specialized and Regulated

118. Nuclear medicine is a highly regulated field. As described by the Nuclear Regulatory Commission, “[b]ecause of their potentially hazardous properties, the use of certain radioactive materials must be closely regulated to protect the health and safety of the public and the environment.” (U.S. Nuclear Regulatory Commission website, <https://www.nrc.gov/about-nrc/radiation/protects-you/reg-matls.html>)

119. The oversight required for the manufacture, distribution and practice of nuclear medicine derives from the highly specialized nature of nuclear medicine.

120. Nuclear medicine refers to medicine (a pharmaceutical) that is attached to a small quantity of radioactive material (a radioisotope). This combination is referred to as a “radiopharmaceutical,” or “nuclear pharmaceutical.”

121. Radiopharmaceuticals target specific organs or cellular receptors, while external detectors capture the radiation emitted from the radiopharmaceutical as it moves through the body in order to generate an image. Diagnosis is based on the way the body is known to handle substances in the healthy state versus a diseased state.

1 122. Radiopharmaceuticals, or nuclear pharmaceuticals, are highly
2 regulated by multiple federal, state, and local agencies.

3
4 123. The Nuclear Regulatory Commission ("NRC") has authority to
5 license and regulate the possession, use, and disposal of nuclear by-product
6 materials, including nuclear pharmaceuticals. The NRC licenses and regulates the
7 use of nuclear by-product materials directly in twenty-one (21) states, and has
8 transferred that authority to state regulatory agencies in twenty-nine (29) states
9 ("the Agreement States"). Thus, under the current regulatory scheme, either the
10 NRC or an Agreement State agency regulates the production, distribution, use of,
11 and disposal of radiopharmaceuticals in a given locale, including by licensing
12 nuclear pharmacists.
13
14
15

16 124. As a result, nuclear pharmacies and nuclear pharmacists who handle
17 radiopharmaceuticals must be highly specialized and are required to meet specific
18 and stringent requirements.
19

20 125. The NRC acts on a specific regulatory scheme that governs the
21 issuance of licenses and administration of radiopharmaceuticals to ensure that any
22 person or entity that may manufacture, produce, acquire, receive, possess, prepare,
23 use or transfer byproduct material for medical use may only do so in accordance
24 with a specific license issued by the NRC or an Agreement State. 10 C.F.R. §
25 35.1, *et seq.*
26
27
28

1 126. Individual nuclear pharmacists must first be licensed by their state
2 boards of medicine and pharmacy before they can apply for authorization from the
3 NRC or from an Agreement State agency to produce, distribute or use nuclear
4 pharmaceuticals as a nuclear pharmacist.
5

6 127. In order to be licensed by the NRC or an Agreement State agency as a
7 nuclear pharmacist, a pharmacist must:
8

9 (a)(1) have graduated from an accredited pharmacy
10 program; (2) hold a current, active license to practice
11 pharmacy; (3) have acquired at least 4000 hours of
12 training/experience in nuclear pharmacy practice; and (4)
pass an examination in nuclear pharmacy; *or*

13 (b)(1)(i) have completed 700 hours in a structured
14 education program consisting of 200 hours of classroom
15 and laboratory training in (A) radiation physics and
16 instrumentation; (B) radiation protection; (C)
17 mathematics pertaining to the use and measurement of
radioactivity; (D) chemistry of byproduct material for
18 medical use; and (E) radiation biology; and (ii)
19 supervised practical experience in a nuclear pharmacy
20 involving (A) shipping, receiving and performing
radiation surveys; (B) using and performing checks for
21 proper operation of instruments; (C) calculating,
assaying, and safely preparing dosages for patients; (D)
22 using administrative controls to avoid medical events in
the administration of byproduct material; and (E) using
23 procedures to prevent or minimize radioactive
contamination; and (2) obtained written attestation from a
24 preceptor authorized nuclear pharmacist that the
25 requirements have been met.

26 10 C.F.R. § 35.55.
27
28

1 128. Similarly, in order to provide radiopharmaceuticals to government
2 agency pharmacies like VA pharmacies, a distributor must be licensed, either by
3 the NRC and/or by the Agreement State, to produce, distribute and use
4 radiopharmaceuticals for human administration. 10 C.F.R. § 35.55
5

6 129. South Carolina, for example, is an Agreement State. Agreement
7 States, have entered into agreements with the NRC that give them the authority to
8 license and inspect byproduct, source, or special nuclear materials used or
9 possessed within their borders.
10

11 130. Any applicant, other than a Federal agency or Federally recognized
12 Indian tribe, who wishes to possess or use licensed material in one of these
13 Agreement States must contact the responsible officials in that State for guidance
14 on preparing an application.
15

16 131. These applications must be filed with State officials, not with the
17 NRC.
18

19 132. At least 38 of Caring Hands' contracts awarded by the VA for the
20 delivery of nuclear pharmaceuticals were awarded in Agreement States (including
21 South Carolina as mentioned above, Alabama, Florida, North Carolina, and Texas).
22

23 133. Radiopharmaceuticals are not only regulated by the NRC and
24 Agreement States, but also by the U.S. Food and Drug Administration ("FDA").
25
26
27
28

1 134. On December 11, 2011, FDA established requirements in 21 C.F.R.
2 Part 212 for the manufacturing of PET radiopharmaceuticals² in accordance with
3 Current Good Manufacturing Practices (“cGMP”) which require firms
4 manufacturing and distributing these drugs to submit either a New Drug Approval
5 (“NDA”) or Amended Drug Approval (“ADA”) to the FDA for approval.
6

7
8 135. Accordingly, the VA made explicit mandatory requirements for those
9 contractors furnishing radiopharmaceutical products and services.

10 136. The VA contracted with Caring Hands and Logmet to manufacture
11 and distribute single unit doses of radiopharmaceuticals and associated materials,
12 including all necessary supplies and packaging, to various VA pharmacies across
13 the country.
14

15
16 137. First, the VA required that these PSMs “shall provide copy of NRC
17 licensure with their bid.” Further, the VA required that “[b]idders/offerors should
18 thoroughly review the specifications and be familiar with the area of coverage
19 prior to submitting their bid/offeror in order to be fully aware of the supplies and
20 services required.” (VA Radiopharma Contracts (“Scope of Work”))
21

22
23 ² Positron emission tomography (“PET”) is a nuclear medicine, functional imaging
24 technique that is used to observe metabolic processes in the body. The system
25 detects pairs of gamma rays emitted indirectly by a positron-emitting radionuclide
26 (tracer), which is introduced into the body on a biologically active molecule.
27
28

1 138. Second, the VA required that the “[c]ontractor shall provide all labor,
2 compounding, supervision, and transportation necessary to provide daily deliveries
3 to the Department of Veterans Affairs,” at the respective pharmacy location.

4
5 139. Third, the VA contracted with these PSMs to perform the necessary
6 quality control procedures and meet all the Nuclear Regulatory Commission,
7 Department of Transportation, FDA, OSHA, and other relevant agency rules and
8 regulations specific to the manufacture and distribution of radiopharmaceuticals.

9
10 140. Fourth, the VA required that the awardees of these contracts “be
11 regularly established in the business that is called for,” and “are able to show
12 evidence of the reliability, ability, experience, equipment, facilities, and personnel
13 directly employed or supervised by them to render prompt and satisfactory
14 service.”

15
16 141. Fifth, the VA required that “[s]upplies shall be handled in accordance
17 with Vendor’s Licensing and NRC Regulations.”

18
19 142. Sixth, the VA required that the “[v]endor shall be responsible for
20 proper disposal/removal of radioactive waste materials or make clear its intention
21 of requiring the VA Medical Centers nuclear medicine service line to dispose and
22 remove.”

23
24 143. Seventh, the VA required that “[a] licensed Radiopharmacist shall be
25 available for consultation inquiries, via telephone during normal duty hours,
26 Monday through Friday, 7:00 am to 5:00 pm.”

1 144. Eighth, the VA required that “[a]ll radiopharmaceuticals supplied by
2 the Vendor shall meet Food and Drug Administration (FDA) and Nuclear
3 Regulatory Commission (NRC) standards for sterility, freedom from pyrogens and
4 contaminants, and radiochemical integrity.”
5

6 145. Ninth, the VA required that “[i]n the event a quality control or
7 material defect is suspected and/or detected by a VA Nuclear Medicine
8 Technologist, the Vendor will be requested to provide any consultation necessary
9 to alleviate any said suspicion and/or defect by the following: (i) provide technical
10 expertise in calibration; (ii) provide professional examination of product, submit
11 recommendation to Contracting Officer; (iii) make expedient replacement of any
12 product suspected of being deficient.”
13
14
15

16 146. The VA solicitations clearly and repeatedly mandated that contract
17 awardees be licensed and have the capability to properly distribute and otherwise
18 handle these highly specialized and regulated radiopharmaceutical products.
19

20 **C. These SDVOSBS Are Acting as Front Companies for Cardinal**
21 **Health**

22 147. These front companies have fraudulently won numerous
23 radiopharmaceutical contracts in partnership with defendants, which are not small
24 businesses and are not entitled to those contracts either alone or as a venture with
25 these front companies.
26
27
28

1 148. The SDVOSB primary contractor does not own, nor have expertise or
2 training in radiopharmaceutical preparation and is not licensed for radiopharmacy
3 or radiation safety protection operations and the safe handling of the radioactive
4 product, according to U.S. and State regulations to protect the patient, the public
5 and the environment.
6

7
8 149. A Fortune 15 company, with 163 radiopharmacies in the 50 states, is
9 the largest single owned radiopharmacy in the competitive space and knows it
10 should stand as its own entity for the bidding/providing of radiopharmaceutical
11 services.
12

13 150. The VA awarded these front companies multiple contracts for the
14 distribution of certain radiopharmaceuticals and related services in Government-
15 owned and operated healthcare facilities because they were SDVOSB and Small
16 Business Set Aside contracts.
17

18 151. In addition, the VA and other federal agencies awarded numerous
19 other unrestricted contracts that required the furnishing of radiopharmaceutical
20 products and related services to Caring Hands to help meet the federal mandate of
21 a three percent quota of contract awards to SDVOSBs.
22
23

24 152. Referenced above, under the 1999 law, at least three percent of the
25 total value of all prime and subcontract awards are required to be awarded to
26 SDVOSBs. 15 U.S.C. § 644(g). Presumably, the contracting officer is expected to
27
28

1 assess whether the SDVOSB could, in fact, perform under the contract before
2 blindly awarding the contract to the entity *because* it is a SDVOSB.
3

4 153. Here, neither of these front companies were entitled to any of those
5 contracts because neither of these front companies are qualified to perform the
6 highly specialized work required by the radiopharmaceutical contracts.
7

8 154. Neither of these front companies are licensed by the NRC or by an
9 Agreement State to possess, use, process, export, and import, nuclear materials and
10 waste, to handle certain aspects of their transportation, or to conduct radiation
11 safety programs for the protection of its employees, the public, or the environment.
12

13 155. Neither of these front companies are licensed to manufacture or
14 handle radiopharmaceuticals or are licensed to operate as a nuclear pharmacy or
15 PET pharmaceutical manufacturer under the FDA current Good Manufacturing
16 Practices (cGMP).
17

18 156. Neither of these front companies could properly prepare doses of
19 these highly dangerous/sensitive radiopharmaceutical products for shipment,
20 including proper storage, shipment, transport, and delivery of these radioactive
21 materials as required by safety standards and the U.S. Department of
22 Transportation.
23

24 157. Neither of these front companies had the certification, expertise, or
25 personnel to properly handle and dispose of waste and used materials, consistent
26 with prescribed safety standards.
27
28

1 158. When these contracts are awarded, the VA expected the proper,
2 prompt and accurate distribution of highly sensitive radiopharmaceutical products.

3
4 159. Neither of their websites include any listing or specific reference to
5 licensed nuclear pharmacists among its employees.

6
7 160. Neither of these front companies maintain the facilities, staff, or
8 expertise to produce, manufacture, transport, or provide radiopharmaceuticals in
9 accordance with NRC/Agreement State, the State Boards of Pharmacy, and/or
10 cGMP regulations.

11
12 161. In fact, Caring Hands' principal place of business is one unit in a strip
13 mall.

14
15 162. Logmet's only business address is 301 Little Gem Court,
16 McDonough, Georgia 30253, which is a single-family home residence.

17 163. Neither of these front companies had a "manufacturing radiation
18 safety officer," responsible for ensuring the safety and compliance of dispensing
19 radiopharmaceutical products.

20
21 164. Neither of these front companies have the capability to operate in
22 multiple jurisdictions.

23
24 165. Neither of these front companies could meet the explicit regulations
25 and inspection requirements of the Nuclear Regulatory Commission.

26
27 166. The NRC provides specific instruction about the requirements of
28 radiopharmaceutical manufacturers, suppliers, and distributors to ensure that

1 “radiopharmaceuticals are being conducted in a manner that will protect the health
2 and safety of workers and the general public [and] are conducted in accordance
3 with USNRC or AS requirements.”
4

5 167. Yet, the VA awarded contracts to both of these front companies in
6 various jurisdictions that are at times, thousands of miles away from where the
7 front company is located. There is no evidence that these front companies were
8 performing any services in those far and away jurisdictions.
9

10 168. Even if you were to assume that these front companies could perform
11 some nominal service, because they hold no qualifications in the area of nuclear
12 pharmacy, that work would be limited to prescription order taking or invoicing.
13

14 169. The prescription order forms include numerous fields of information
15 such as patient name, the drug type, order amount, the dosage, and the physician,
16 among other fields.
17

18 170. The prescription form is completed in real-time in the pharmacy and
19 is physically attached to the barrel of the syringe that contains the radioactive
20 pharmaceutical drug.
21

22 171. Simultaneous with completing the prescription form, an invoice must
23 be completed that includes all the same information as the prescription order form.
24

25 172. Both the prescription order form and the invoice are based on the
26 actual prescription the radiopharmacist receives at the time the drug must be filled.
27
28

1 173. The radiopharmacist is the only qualified person who can ensure that
2 the amount, dosing, and actual drug dispensed is accurate.

3
4 174. Similar to any pharmacy practice, the turnaround time between when
5 the prescription is given to the pharmacy and ultimately filled for the patient can be
6 as quick as two hours or less.

7
8 175. This work cannot be completed remotely or electronically from
9 another location.

10 176. In a majority of the contracts awarded to Caring Hands and Logmet,
11 the dispensing pharmacy was located in a different state from where those front
12 companies' principal places of business.

13
14 177. There is also no indication or proof that they are performing either of
15 these services.

16
17 178. Moreover, the security of such patient information being exchanged
18 between the VA pharmacy and these front companies in an electronic or other form
19 is questionable and may give rise to violations of the Health Insurance Portability
20 and Accountability Act or HIPAA that provides for data privacy and security to
21 safeguard patients' medical information.

22
23
24 179. These VA pharmacies could not have sent prescriptions to these sham
25 front companies with protected health information without a properly executed
26 Business Associate Agreement (BAA) pursuant to HIPAA.

27
28 180. These SDVOSBs did not execute any BAAs.

1 181. Both of these front companies falsely certified to the Government that
2 they are licensed to possess, use, process, export, manufacture, or import nuclear
3 materials and waste and/or handle certain aspects of their transportation, and, thus,
4 able to perform contracts for nuclear pharmaceuticals awarded under the "Small
5 Business Set Asides" Program.
6

7
8 182. Contrary to the SBA's intent that small businesses perform at least 50
9 percent of the work, 13 C.F.R. § 125.6, in these arrangements, the small business
10 prime contractors (or front companies) are performing a de minimis amount of
11 work because they cannot furnish radiopharmaceutical products or services.
12

13 183. Instead, these front companies have to necessarily pair with Fortune
14 500 companies like Cardinal Health to perform on these radiopharmaceutical
15 contracts.
16

17 184. Indeed, a GE Healthcare representative who manufactures and
18 distributes these radiopharmaceutical products confirmed that Cardinal Health has
19 some kind of "internal arrangement" with Caring Hands when another SDVOSB
20 accused GE of pairing with Caring Hands who was not a licensed radiopharmacy.
21

22 185. The GE Healthcare representative stated in email:
23

24 To attempt to answer your question, I will say it is my
25 understanding CaringHands is a subsidiary or exclusive
26 agent of Cardinal Health [CH]. I'm sure they have some
27 specific arrangement to have CH to service their [sic] all
28 of their contracts, which is an arrangement between
CaringHands and CH and has nothing to do with GE.
We sell to CH, who has distribution rights to GE and

1 many other products, including contrast media and
2 devices, and there is likely a contract between those
3 entities. We do not contract with CaringHands, only
4 Cardinal Health.

5 Email from James Kaufman, GE Healthcare Executive Global Leader,
6 to Perry Polsinelli, Mystic Ventures Owner (August 26, 2015).

7 186. Pairing or partnering on small business set aside contracts is not
8 categorically prohibited but there are clear specifications on how it can be done.
9

10 187. In the event that the small business prime does not itself manufacture
11 the product, the product must still only be supplied by another small business
12 (“non-manufacturer rule”). 15 USC § 637(a)(17); 13 C.F.R. § 121.406 (emphasis
13 added).
14

15 188. The size of a business – whether it is considered “small” pursuant to
16 SBA regulations – is determined by the NAICs code affiliated with that line of
17 business. 13 C.F.R. § 125.1.
18

19 189. These VA contract solicitations use the NAICs code 325412, which is
20 defined as pharmaceutical preparation manufacturing.
21

22 190. The SBA has established a threshold of the number of employees that
23 a small business soliciting contracts for pharmaceutical preparation manufacturing
24 with NAICS code 325412 must not exceed, which is 1,250.
25
26
27
28

1 191. Cardinal Health 414, LLC has 3,000 employees and Cardinal Health,
2 Inc. has 37,300 employees. Neither qualify as “small businesses” for contracts
3 with NAICS code 325412.
4

5 192. The SBA also contains provisions that allow the Administrator of the
6 SBA to waive this requirement when there are no small business manufacturers or
7 processors available to supply the product to the Federal Government.
8

9 193. Here, UPPI’s 87 members represented at least 87 small business
10 manufacturers or processors who had the necessary license and could have
11 properly fulfilled all the contractual requirements to supply these
12 radiopharmaceutical products pursuant to these VA contracts.
13

14 **1. Caring Hands**

15
16 194. According to its website, Caring Hands has ten employees, has a
17 principal place of business in Ridgeland, South Carolina, and has won over \$85
18 million in federal contracts over the last several years.
19

20 195. On its registration page with the System for Award Management or
21 SAM, Caring Hands identifies eight “plant” location addresses. Each location lists
22 Obie Bacon as the owner, and identifies the owner address as the location in
23 Ridgeland, South Carolina. None of these locations appear to have the capability
24 to function as a radiopharmaceutical supplier, distributor, or processor.
25

26
27 196. Caring Hands’ primary place of business as advertised on the website
28 is in Ridgeland, South Carolina.

1 197. Caring Hands then lists eight other purported places of business in
2 South Carolina, Georgia, and Alabama.

3
4 198. The first location listed on the SAMs website is at 3516 South Live
5 Oak Drive, Suite E, Moncks Corner, South Carolina 29461. The address is in a
6 strip mall shopping center.

7
8 199. The second location listed on the SAMs website is 1240 First Street
9 South Extension, Suite D, Columbia, SC 29201. Again, this location is in a strip
10 mall shopping center location and appears to be a storage facility.

11
12 200. The third location listed on the SAMs website is at 2215 9th Avenue,
13 Suite B, North Port, AL 35475., which appears to be a storage unit that does not
14 appear to have the capability to house highly toxic radiopharmaceutical products
15 that require refrigeration.

16
17 201. The fourth location listed on the SAMs website is at 109 Troup Street
18 Bldg., Dublin, GA 31021. The building simply has automobile bays to store and
19 wash vans. There is no product that is (or could be) stored at this location.

20
21 202. The fifth location listed on the SAMs website is at 2740 Apple Valley
22 Rd NE, Atlanta, GA 30319 and is identified as the “Brookhaven Self Storage
23 Unit.” It similarly appears to be a storage facility or warehouse that could not
24 house or store any radiopharmaceutical products.

25
26 203. The sixth location listed on the SAMs website is at 3105 Spring Grove
27 Drive, Suite C-3, Augusta, GA 30906 and is identified as “Dean’s Bridge
28

1 Industrial Park Space for Lease Facility.” It again appears to be a storage facility
2 or warehouse that could not house or store any radiopharmaceutical products.
3

4 204. The seventh location listed on the SAMs website is at 812 Oliver
5 Court, Montgomery, AL 36117. This location also appears to be another storage
6 facility that could not house or store any radiopharmaceutical products.
7

8 205. The eighth location listed on the SAMs website is at 621 Graymont
9 Avenue, Birmingham, AL 35203. Once again, the location is a warehouse that
10 leases space and does not appear to house any retail, manufacturing, or office
11 space. Once again, the location does not appear to be able to house or store any
12 radiopharmaceutical products.
13

14 206. From 2013 to the present, Caring Hands solicited and was awarded *at*
15 *least* 14 contracts and numerous modifications on those contracts (Contract ID
16 Numbers: VA24614D0022; VA24614J0473; VA24615J0044; VA24715P1634;
17 VA24714C0365; VA24815D0013; VA24815J0210; VA24815J1387;
18 VA24815J1468; VA24815J2352; VA24814D0216; VA24815J0203;
19 VA25717D0008; VA25717J0143; in addition to the multi-year contract options
20 applicable to some contracts) for a total of 38 contract terms to provide
21 radiopharmaceuticals to the VA for a total contract award amount of over \$5.9
22 million. (Caring Hands Updated Radiopharmaceutical Contract Awards)
23
24
25
26
27
28

1 207. At least 14 of the contracts identified above were awarded as “sole
2 source” or “simplified acquisition” awards based on Caring Hands’ status as a
3 SDVOSB and/or Small Business and were excepted from open competition.
4

5 208. All of the contracts required the contract awardee to manufacture,
6 distribute and deliver radiopharmaceutical supplies
7

8 209. Caring Hands could not perform on these contracts because Caring
9 Hands did not have the mandated radiopharmacy licensure, personnel, or vehicles.
10

11 210. First, Caring Hands is not licensed with the Nuclear Regulatory
12 Commission or with an Agreement State and is not regularly established in the
13 business of providing radiopharmaceuticals.
14

15 211. Second, Caring Hands does not have the required personnel to
16 perform the work or render the necessary quality control procedures.
17

18 212. Third, Caring Hands’ delivery vans provide no indication that they
19 safely transport radioactive pharmaceuticals and bear no warning or precautions
20 that the vans transport those types of pharmaceuticals. Properly certified vehicles
21 include refrigerated units and bear explicit radioactive symbols because of the
22 dangerous and potentially toxic substances the vehicle is transporting.
23

24 213. Fourth, Caring Hands’ principal place of business in South Carolina is
25 a 300-square foot office space with no indication or appearance for pharmaceutical
26 repackaging or dispensing, let alone radiopharmaceutical processing.
27
28

1 214. Fifth, Caring Hands was awarded contracts in cities nowhere near a
2 Caring Hands location. Putting aside the fact that all of the Caring Hands'
3 locations looked like sham store fronts, even if one were to assume they were
4 legitimate enterprises, those "places of business" were nowhere near the twelve
5 contracts or modifications awarded to Caring Hands to furnish radiopharmaceutical
6 products to VA pharmacies in the Miami, Florida region in the amount of over
7 \$3,500,000.
8

9
10 215. Caring Hands also was awarded an additional 56 contracts or contract
11 modifications from the VA and other federal agencies to furnish medical
12 equipment and supplies in South Carolina, Kentucky, Georgia, Alabama, and
13 Connecticut.
14

15
16 216. UPPI has reasonable suspicion that Caring Hands is likely not
17 performing a majority of the work, if any, on those contracts.
18

19 217. Caring Hands did not and could not have performed at least fifty (50)
20 percent of the cost of the contract incurred for personnel with its own employees,
21 and did not and could not have performed at least fifty (50) percent of the cost of
22 manufacturing the supplies or products.
23

24 2. **Logmet**

25 218. Logmet certified its principal place of business as 301 Little Gem
26 Court, McDonough, Georgia 30253, which is a single-family home residence.
27
28

1 219. In its System for Award Management or SAM registration, Logmet
2 certified that it does not intend to use any other plants or facilities located at a
3 different address than this single-family residence in the fulfillment of its contract
4 award.
5

6 220. Over the last 3 years Logmet has certified in its SAM Registration that
7 the contractor consists of “1 employee” and “annual revenue of \$1.”
8

9 221. Logmet advertises, however, that it “offer[s] over 300,000 medical
10 and dental supplies, equipment, products and devices to meet[] your organizational
11 needs.”
12

13 222. Further, Logmet certifies that it can fulfill contracts that require highly
14 specialized and varied services from cutting and sewing apparel to
15 radiopharmaceutical manufacturing and preparation.
16

17 223. The VA awarded Logmet six radiopharmaceutical contracts or
18 contract modifications in 2016 and 2017 for a total contract award amount of
19 approximately \$465,000.
20

21 224. The six contracts list the principal places of performance in
22 Massachusetts, New Mexico, and Georgia.
23

24 225. All six contract awards were SDVOSB set aside or sole source
25 contract solicitations.
26

27 226. Other federal agencies including the Centers for Disease Control and
28 Prevention and the Department of the Army have also awarded Logmet

1 approximately eight contract awards or modifications for radiopharmaceutical
2 products for total contract award amounts of over \$9.9 million.

3
4 227. One of the places of business for those other agency contracts is
5 Croatia.

6 228. Logmet does not advertise any place of business in Croatia.

7
8 229. Logmet could not perform on these contracts because Logmet did not
9 have the mandated radiopharmacy licensure, personnel, or vehicles.

10 230. First, Logmet is not licensed with the Nuclear Regulatory
11 Commission or an Agreement State and is not regularly established in the business
12 of providing radiopharmaceuticals.

13
14 231. Second, Logmet does not have the required personnel to perform the
15 work or render the necessary quality control procedures.

16
17 232. Third, Logmet's principal and only identified place of business in
18 Georgia is a single-family residence with no indication or appearance for
19 pharmaceutical repackaging or dispensing, let alone radiopharmaceutical
20 processing.

21
22 233. Fourth, Logmet was awarded contracts in locations nowhere near its
23 single-family residence address in Georgia.

24
25 234. Logmet also was awarded an additional 56 contracts or contract
26 modifications from the VA and other federal agencies to furnish medical
27

1 equipment and supplies in Mississippi, Missouri, Utah, New Mexico, Colorado,
2 Massachusetts, Texas, Florida, Louisiana, Ohio, and Georgia.

3
4 235. UPPI has reasonable suspicion that Logmet is likely not performing a
5 majority of the work, if any, on those contracts.

6
7 236. Logmet did not and could not have performed at least fifty (50)
8 percent of the cost of the contract incurred for personnel with its own employees,
9 and did not and could not have performed at least fifty (50) percent of the cost of
10 manufacturing the supplies or products.

11
12 237. Defendants knowingly submitted, caused to be submitted, and
13 conspired to submit false claims for payment to the Government, in violation of the
14 FCA.

15
16 **3. Cardinal Health – SDVOSB Fraudulent Partnership**
17 **Scheme**

18 238. To perform on these contracts, Caring Hands and Logmet entered into
19 agreements with Cardinal Health under which Caring Hands and Logmet would
20 bid on both Small Business Set-Aside and unrestricted contracts for the provision
21 of nuclear pharmaceuticals. The expectation was that Cardinal Health would, in
22 fact, perform on the contracts.

23
24 239. To encourage Caring Hands and Logmet to engage in this partnership
25 or “team” arrangement, Cardinal Health paid these sham front companies a
26 percentage fee share from the total contract award.
27
28

1 240. The kickback or remuneration paid to Caring Hands, for instance, was
2 so significant that Caring Hands declared an annual revenue of \$61.7M in 2014.

3
4 241. In 2014, Caring Hands still only had 11 employees and was run by
5 Obie Bacon and his wife.

6 242. Other than bidding on and obtaining the contracts as SDVOSBs,
7 Caring Hands' and Logmet's only responsibilities under the contracts was to
8 submit the claims for payment in order to make it appear that Caring Hands had
9 performed the contract and to conceal that Cardinal Health had actually performed
10 the contract.
11

12
13 243. By contrast, Cardinal Health performed a majority of the work.

14 244. Cardinal Health could perform all the work required under these
15 contracts because Cardinal Health operates "the largest radiopharmaceutical
16 network in the United States."
17

18 245. As of October 2016, Cardinal Health, Inc. was ranked #15 on the list
19 of Fortune 500 companies, with more than \$102.5 billion in revenue and more than
20 \$1.2 billion in profits.
21

22 246. Cardinal Health did not bid on, and was not awarded, the contracts at
23 issue and was neither eligible for, nor entitled to receive, any benefits under
24 SDVOSB Set-Asides, sole source, or simplified acquisition awards.
25

26 247. Instead, Cardinal Health and Caring Hands used Caring Hands' and
27 Logmet's preferred status as SDVOSBs to obtain Government contracts
28

1 fraudulently, knowing that neither Caring Hands nor Logmet could perform the
2 contracts and that Cardinal Health was ineligible to bid on the contracts.

3
4 248. Moreover, Cardinal Health furnished the warranty for all the
5 radiopharmaceutical products transported and disbursed pursuant to the these sham
6 SDVOSB contract awards.

7
8 249. Because these radiopharmaceutical products are highly dangerous
9 substances, the VA pharmacy solicitations require that the contract awardee insure
10 its services with a warranty. (VA Contract Solicitation No. VA247-15-Q-0193
11 (Birmingham Contract) at Section E.1 52.212-1(b) (Instructions to Offerors –
12 Commercial Items) (“Submit signed and dated offers to the office specified in this
13 solicitation . . . [a]s a minimum, offers must show – (5) Terms of any express
14 warranty.”))
15
16

17 250. Cardinal Health similarly understood the importance of warranties in
18 the provision of these products.
19

20 Cardinal Health warrants to customer that the
21 pharmaceutical products prepared or compounded by
22 Cardinal Health shall, upon delivery, be free from defects
23 in material and workmanship caused by Cardinal Health.
24 Customer must promptly notify the dispensing pharmacy
25 of any alleged defect. The exclusive remedy under this
26 warranty shall be the replacement of the defective
27 product or the refund of the purchase price paid for the
28 defective product, at cardinal health’s option. **Cardinal
Health Disclaims all other warranties, express or
implied, including any warranty of merchantability.**
Cardinal Health does not warrant pharmaceutical
products manufactured by others and provided to

1 customer without preparation or compounding by
2 Cardinal Health, but Cardinal Health hereby assigns to
3 customer the manufacturer's warranties to the extent such
4 warranties are assignable. Cardinal Health shall not be
5 liable for indirect, special, incidental, or consequential
6 damages, whether under contract or in tort, arising out of
7 its performance under this agreement.

8 Cardinal Radiopharmaceutical Supply Agreement at para.12.

9 251. None of these sham SDVOSBs, including namely Caring Hands and
10 Logmet, have warranties, and, if they did, the warranties would be false statements.

11 252. UPPI engaged the radiology department at the Durham, Virginia VA
12 facility after they awarded a radiopharmaceutical contract to Caring Hands.

13 253. In particular, UPPI representatives spoke with Jim Stanfield, who is
14 the VA Chief Tech at that location. Although the contract was awarded to Caring
15 hands, Stanfield informed UPPI that he was pleased with the work Cardinal Health
16 was performing on the contract.

17 254. When the UPPI representative stated that the contract had been won
18 by Caring Hands, not Cardinal Health, Stanfield became quiet and said that the
19 UPPI representative would need to speak to the VA contracting officer because
20 Stanfield was simply the end user.

21 255. The contracting officer on the Durham, Virginia radiopharmaceutical
22 contract was Olin Newsome.

23 256. UPPI representatives understand that Newsome may have a personal
24 relationship with Obie Bacon.

1 257. On LinkedIn, Newsome endorsed the skill set of an Economically
2 Disadvantaged Women Owned Small Business owner, Nikita Davis.

3
4 258. The U.S. Attorney's Office in the District of Columbia successfully
5 prosecuted Davis for a fraudulent contract procurement scheme, and she was
6 sentenced to twenty months in prison on October 20, 2017.

7
8 259. These contracts were not performed in accordance with Small
9 Business and/or SDVOSB performance standards, by Caring Hands or Logmet.
10 The contracts were performed by Cardinal Health.

11
12 260. For all claims for payment submitted pursuant to the fraudulently
13 awarded contracts after June 30, 2016, Cardinal Health was not "similarly situated"
14 much less properly "small" for the NAICS code assigned to the contracts, which
15 were performed in violation of the LOS.

16
17 **D. Cardinal Health Made Further False Statements About Its and**
18 **Front Companies' LEU Capabilities in the Award of Contracts**

19 261. The Government has made it a national priority to reduce and protect
20 vulnerable nuclear and radiological material located at civilian sites worldwide,
21 including by converting research reactors and isotope production facilities, from
22 the use of high energy uranium ("HEU") to low energy uranium ("LEU").

23
24 262. On January 2, 2013, Congress passed the American Medical Isotope
25 Production Act of 2011, P.L. 112-239, to promote the production of molybdenum-
26

1 99 ("Mo-99"), the parent nuclide of Tc-99m, with non-HEU or LEU in the United
2 States.

3
4 263. Mo-99 is produced in nuclear research reactors using *either* HEU *or*
5 LEU.

6
7 264. For Tc-99m to be in compliance with the non-HEU requirement,
8 however, *both* the uranium targets and the uranium fuel used to produce Mo-99,
9 must be comprised of LEU.

10
11 265. It is not, therefore, technically acceptable to use HEU in any of the
12 processes to produce the medical isotopes, if the Mo-99 (and Tc-99m) are to
13 qualify as derived from LEU; *the entire process from the reactor to the imaging*
14 *center must use only LEU.*

15
16 266. The Centers for Medicare and Medicaid Services in its effort to assist
17 in the elimination of highly enriched uranium created reimbursement code Q9969
18 and requires >95% LEU.

19
20 267. On January 3, 2014, the Under Secretary of Health for the VA, Dr.
21 Robert Pretzel sent a Memorandum to Network Directors at the request of The
22 White House Interagency Policy Committee regarding the preferential
23 procurement of non-High Enriched Uranium-Derived Medical Isotopes to improve
24 national security and eliminate HEU medical isotopes that are a risk to nuclear
25 proliferation.
26

27
28 268. The January 3, 2014 Memorandum stated:

1 (1) The White House Interagency Policy Committee has
2 requested that the Department of Veterans Affairs (VA)
3 preferentially procure medical radioisotopes from non-
4 High Enriched Uranium (HEU) sources. The reason for
5 this request is that transportation and storage of HEU by
6 radioisotope vendors may be a security and nuclear
7 proliferation risk. VA's leadership in the transition to
8 non-HEU radioisotope production will improve national
9 security, promote the creation of domestic suppliers of
10 medical radioisotopes, and will ultimately reduce the
11 United States' reliance on foreign sources. In support of
12 this important initiative, I am asking you to purchase
13 non-HEU derived isotopes when they become
14 commercially available.

15 ***

- 16 (3) As a point of clarification, VA does not purchase
17 uranium. The radioisotope vendors purchase uranium to
18 generate Tc-99m. Whether Tc-99m is made with HEU
19 or non-HEU, the radioisotope is the same. Therefore,
20 transition to a non-HEU vendor will not otherwise affect
21 your operations.
- 22 (4) Please notify all Veterans Health Administration
23 Veterans Integrated Service Network Chief Medical
24 Officers, Quality Management Officers, Chiefs of Staff,
25 and facility nuclear medicine staff to begin preferential
26 procurement of Tc-99m produced from non-HEU sources
27 as adequate supplies become available.

28 269. On March 28, 2016, a second preferential procurement from the
Under Secretary of Health for the VA, Dr. David J. Shulkin, was sent to Network
Directors further reiterating that many radioisotopes vendors have converted to
LEU operations.

270. The March 28, 2016 Memorandum stated:

1 (1) Many radioisotope vendors have converted to Low
2 Enriched Uranium (LEU) operations, thus reducing the
3 United States' reliance on foreign sources. In 2014, my
4 office encouraged you to purchase radioisotopes from
5 vendors using LEU sources. I am reminding you of our
6 commitment and encouraging you to expand preferential
7 purchases to the greatest extent practical.

8 ***

9 (3) Currently, about 20 percent of VA medical centers
10 purchase Tc-99m from radioisotope vendors using LEU
11 sources. Since 2012, the number of vendors has
12 increased. Each year, vendors should be surveyed for
13 LEU capability via sources sought request. Our practice
14 must be to solicit Tc-99m as LEU capability emerges.

15 271. Consistent with the VA Under Secretary memos, most if not all of the
16 VA contracts at issue here required the provision of radioisotopes from non-Highly
17 Enrichment Uranium (non-HEU) or LEU sources.

18 272. More to the point, the solicitations at issue here unequivocally
19 required non-HEU (LEU) Tc-99m: **"6.8 *** Tc-99M REQUIREMENT FOR**
20 **ALL VA MEDICAL CENTERS: Tc-99m to be produced by the low enriched**
21 **uranium method only.***"** VA Solicitation No. VA258-15-N-0559, Phoenix
22 Nuclear Medicine – Radio-pharmaceuticals 5 yr. IDIQ (6-22-2015).

23 273. The VA is required to determine whether the proposal meets technical
24 acceptability requirements.
25
26
27
28

1 274. Technical acceptability under this solicitation requires the successful
2 contractor to be capable of providing non-HEU Tc-99m doses to the Nuclear
3 Medicine Departments on a daily consistent and reliable basis.
4

5 275. Cardinal Health acknowledged that the entire radiopharmaceutical
6 industry needed to convert 100 percent of its product to non-HEU. Cardinal
7 Health Disclosure, December 21, 2012.
8

9 276. Indeed, Cardinal Health is the largest nuclear pharmacy company in
10 the United States with 163 locations. (Cardinal Health website)
11

12 277. As of November 8, 2017, less than 10 percent of those locations have
13 >95% non-HEU Mo99 generator product every working day of the month.
14

15 278. In 40 of 77 UPPI member pharmacies supply LEU - the government
16 mandated radioisotope that replaces HEU - on a consistent and uninterrupted basis.
17

18 279. Even if Cardinal Health properly won any of these contracts, Cardinal
19 Health procured the contract on at least the false pretense that it could furnish the
20 mandated non-HEU product when, in fact, it could not.
21

22 280. Cardinal Health's false representation of its LEU capabilities in the
23 solicitation and award of VA contract awards renders all those contract award
24 payments false.
25

26 281. Neither Cardinal Health, nor any of the sham SDVOSBs it used as
27 fronts, could acquire, possess and supply the necessary non-HEU product raising
28

1 concerns about the manner in which those procurements were conducted and the
2 VA's commitment to patient safety and nuclear safety.

3
4 **E. Scierter: Defendants Knowingly Violated the False Claims Act**

5 282. Cardinal Health's primary interest in pairing with these PSMs as
6 subcontractors was to gain an unfair advantage in the award of these contracts.

7
8 283. Cardinal Health engaged in these agreements with full knowledge that
9 the PSMs could not perform much of any work under the contract and certainly
10 could not act on 50 percent or more of the contract service and supply obligations.

11
12 284. Instead, Cardinal Health intended to hide behind the small business
13 designations of Caring Hands and Logmet and capitalize on the federal and judicial
14 mandates for preferential contract awards to small businesses and, in particular,
15 SDVOSBs.

16
17 285. Cardinal Health's opportunistic and intentionally misleading conduct
18 meant that the VA, at times, did not even realize that it was Cardinal Health
19 performing on the contract under the cloak of a SDVOSB's sham storefront.

20
21 286. Relator believes that Cardinal Health has and continues to use other
22 SDVOSBs as front companies to trigger and ultimately win government agency
23 contract awards with the intent to perform a majority of the work on the contracts.

24
25 287. Pairing and otherwise hiding behind SDVOSBs gives Cardinal a
26 competitive advantage and almost exclusivity in the radiopharmacy market it
27 already dominates based on its size.
28

1 **1. Cardinal Health Knowingly and Fraudulently Exploited the**
2 **Government's Preference for Awarding Contracts to**
3 **SDVOSBs**

4 288. At least twenty of the contracts awarded to Caring Hands and Logmet
5 were small business or SDVOSB set asides, meaning that Cardinal Health could
6 not have been awarded those contracts and should not have performed more than
7 50% of the work on those contracts.
8

9 289. For the rest of the contract awards, Defendants fraudulently took
10 advantage of the legislative, executive, and judicial pressure to meet small business
11 quotas.
12

13 290. In all of those instances, Defendants were clearly violating SBA
14 mandates and laws intended to help small businesses, and, particularly, service
15 disabled veteran owned small businesses.
16

17 291. The VA pharmacies and contracting officers would afford preference
18 to SDVOSB entities competing for contract awards in the radiopharmaceutical
19 context because of pressure they felt in meeting the Congressionally mandated
20 quotas and what they understood as a court ordered mandate in the Supreme Court
21 *Kingdomware* decision.
22

23 292. On May 24, 2017, UPPI representatives attended the HealthConnect
24 Reverse Expo in Atlanta, GA -- a forum for commercial vendors of radiology and
25 IT products and services -- to meet with federal agency representatives tasked as
26 purchasing agents for radiopharmacies like the hundreds maintained by the VA.
27
28

1 293. UPPI representatives spoke with Mr. Hollis A. Tessmer, II, a business
2 manager and technical director of imaging services at the Charlie Norwood VA
3 Medical Center in Augusta, GA.
4

5 294. UPPI representatives were inquiring about if and how the VA was
6 fulfilling the preferential procurement memoranda of LEU (or non-HEU) medical
7 isotopes.
8

9 295. Tessmer confessed to having no knowledge of a non-HEU preference
10 in nuclear pharmacy contracting and instead asked the UPPI representatives if they
11 were aware of the Supreme Court *Kingdomware* decision.
12

13 296. Tessmer then explained that in order to win a VA radiopharmaceutical
14 solicitation, UPPI members would need to partner with SDVOSBs.
15

16 297. UPPI representatives again spoke with Tessmer at the HealthConnect
17 Radiology Imaging Conference in Chicago, IL on October 20, 2017.
18

19 298. Tessmer again encouraged the small business members of UPPI to
20 pair with a SDVOSB to win VA contract awards, and specifically referred UPPI
21 representatives to Thomas Childers, who formerly operated an SDVOSB and could
22 otherwise help other businesses with this scheme.
23

24 299. Childers' SDVOSB was called Heritage Resource Group with DUNS
25 963383257 and a business address that was a residence in Cumming, GA.
26

27 300. Tessmer explained that when contracting officers are aware of a
28 SDVOSB bidder for a particular contract, there is no competitive process or choice

1 as to the winning bid. The SDVOSB is awarded the contract automatically
2 because of pressure felt from *Kingdomware*.

3
4 301. Tessmer explained that while the SDVOSB may be the prime
5 contractor in name, the SDVOSB is simply a pass through for a different entity to
6 actually perform the work.

7
8 302. Tessmer implied that this type of sham arrangement works in the
9 small business subcontracting arena because there is no obligation on a prime
10 small business to submit any formal subcontracting plan.

11
12 303. Tessmer explained that the SDVOSB is paid 10 – 20 percent of the
13 contract award for acting as a pass through.

14
15 304. When UPPI asked how the unqualified SDVOSB can be awarded
16 these highly specialized radiopharmaceutical contracts, Tessmer responded that the
17 SDVOSB can represent that it has a nuclear pharmacy license because the
18 SDVOSB is in a joint venture with a licensed entity.

19
20 305. Tessmer acknowledged that the SDVOSB is not doing any of the
21 work and is only being used for the actual contractor to “check a box,” and further
22 acknowledged the possible impropriety of the business venture stating that “you
23 gotta be in bed with this individual. This has got to be somebody you trust.”

24
25 306. Tessmer further acknowledged that Cardinal Health may be engaged
26 in this game acting as the larger licensed conglomerate behind the SDVOSB prime
27 stating, “It’s a game. Cardinal may not be playing the game very well. Yet they’re
28

1 a huge conglomerate. It doesn't take much, you just got to play the game," and
2 have the ability to "check a box."
3

4 307. Under no uncertain terms, Tessmer was informing UPPI (with a
5 wink and a nod) that SDVOSBs, irrespective of, and in fact, because of their
6 lack of qualification or capability to render these radiopharmaceutical
7 services, were given preferential treatment and ultimately, awarded these
8 contracts because the VA was aware that a larger conglomerate would
9 actually perform the contract services.
10
11

12 2. Cardinal Health Fraudulently Triggered the Rule of Two

13 308. But partnering with sham front SDVOSBs was not enough to
14 guarantee Cardinal Health a contract award.
15

16 309. Cardinal Health needed to trigger the Rule of Two particularly if the
17 contract was unrestricted.
18

19 310. If Cardinal Health was able to show the contracting officer that there
20 were at least two SDVOSBs who intended to bid on the contract solicitation, the
21 Rule of Two would be triggered ensuring that at least one of those two SDVOSBs
22 would be awarded the contract.
23

24 311. In reality, there were never two or more SDVOSBs who were
25 qualified to submit bids for these radiopharmaceutical contracts because there were
26 never two or more SDVOSBs who had the necessary licensure, staff, facilities, or
27 equipment to furnish these highly specialized, radioactive products.
28

1 312. Indeed, there were often no SDVOSBs who could perform this work.

2 313. But that did not stop Cardinal Health on fraudulently capitalizing on a
3
4 rule that contracting officers felt compelled to act upon and restrict competition for
5 these highly specialized contracts.

6 314. Through this fraudulent scheme, Cardinal continues to restrict
7
8 competition and maintain a monopoly on the nuclear pharmacy market.

9 315. Cardinal learned of all the SDVOSBs who were attempting to appear
10
11 competent, licensed, and qualified to distribute radiopharmaceutical products
12 through a simple search on the "Interested Business Vendor List" published on the
13 VA Department website.

14 316. The "Interested Business Vendor List" is where businesses self-certify
15
16 their area of expertise and qualifications by NAICS Codes and self-certify their
17 business type, including SB and SDVOSB, among other types of business
18 certifications.

19 317. Cardinal may have initially discovered Caring Hands and Logmet
20
21 from this list.

22 318. Cardinal likely learned of another SDVOSB - Standard Medical
23
24 Equipment Systems, LLC ("Standard Medical") – that self-certified that it was an
25 SDVOSB with expertise and personnel qualified in the business of
26 radiopharmaceutical products (NAICS Code 325412) on an Interested Business
27 Vendor List for a given contract.
28

1 319. Like Caring Hands and Logmet, Standard Medical was not qualified
2 to furnish these highly specialized services.

3
4 320. Standard Medical advertises itself as a “certified minority (MBE)
5 Veteran (SDVOSB) owned company” established by Anthony B. Goodesmith in
6 2005 “to deliver high quality medical devices and laboratory equipment.

7
8 321. Standard Medical has one page indicating that it can offer
9 radiopharmaceuticals.

10 322. Standard Medical has a principal place of business at 8160 Maple
11 Lawn Blvd, Unit #500, Fulton, MD 20759.

12 323. That place of business appears to be an office suite.

13
14 324. Although Standard Medical was referenced on multiple
15 radiopharmaceutical solicitations as an interested business vendor, it did not win
16 any of those contracts.

17
18 325. Standard Medical may have accepted remuneration from Cardinal
19 Health to be another SDVOSB that would trigger the application of the rule of two
20 and compel the contracting officer to ultimately award the contract to a sham
21 SDVOSB acting on behalf of Cardinal Health like Caring Hands or Logmet.
22

23
24 **3. When Challenged, the VA Terminated Contract Awards**
25 **with Caring Hands and Logmet**

26 326. To the extent Cardinal Health claims there was any confusion or
27 ignorance as to these PSMs’ capabilities, the VA on at least three occasions upheld
28

1 protests filed by UPPI members and withdrew or terminated contract awards to
2 Caring Hands and Logmet.

3
4 327. In September 2016, Shertech Pharmacy Charlotte, LLC, a UPPI
5 member, filed a pre-award protest against the Department of Veterans Affairs
6 Multiple Delivery Sites of Care in North Carolina including W.G. Hefner VA
7 Medical Center, Salisbury, NC; Charlotte Health Care Center, Charlotte, NC; and
8 Kernersville Health Care Center, Kernersville, NC pursuant to Solicitation No. VA
9 246-16-Q-1208.
10

11
12 328. Shertech Pharmacy is a small, woman-owned business, which is
13 headquartered in Charlotte, North Carolina, and is a properly licensed entity that
14 furnishes radiopharmaceutical products.
15

16 329. Solicitation No. VA 246-16-Q-1208 was for the manufacture and
17 distribution of radiopharmaceuticals used for diagnostic imaging services and
18 functional studies of organs (identified with NAICs code 325412) and was a 100
19 percent small business set aside for SDVOSBs.
20

21 330. In submitting its pre-award protest on August 18, 2016, Shertech
22 stated that it was unreasonable to set aside the contract for a SDVOSB when there
23 was no SDVOSB who held the proper licensing to provide the necessary services
24 within the required logistical area of the VA pharmacies.
25
26
27
28

1 331. Shertech specifically noted that the SDVOSBs listed on the Interested
2 Vendors List for this Solicitation “were not companies that could perform the
3 services requested.”
4

5 332. In particular, Shertech stated “that the companies on the Interested
6 Vendors List are not licensed to receive, possess, manufacture, prepare
7 radiopharmaceuticals combining Tc-99m with the radiopharmaceutical ligand,
8 perform quality control,” among other deficiencies.
9

10 333. Most notably, Shertech informed the Contracting Officer that none of
11 the listed SDVOSBs possessed the necessary NRC licensure.
12

13 334. Because the radioactive material used for individual patient doses are
14 very short- lived (majority have 6-hour half-lives), the dispensing pharmacy must
15 be within about a two-hour radius of the Nuclear Medicine department otherwise
16 the radiopharmaceuticals “would be significantly deteriorated to an unusable
17 dosage strength.”
18
19

20 335. The contracting officer for Solicitation No. VA 246-16-Q-1208
21 responded on September 6, 2016 stating that “[t]here is no actual solicitation at this
22 time (still in the pre-solicitation phase); however, there are no plans to change the
23 set-aside requirement at this time.” Email from D. Hurlock (VA Contracting
24 Officer) to K. Sheriff (Shertech Pharmacy representative), Re: Salisbury VA
25 Radiopharmaceuticals VA 246-16-Q-1208, dated September 6, 2017.
26
27
28

1 336. After a month and likely because of the protest, the contracting officer
2 (D. Hurlock) temporarily suspended the new radiopharmaceutical product
3 solicitation for the Salisbury VA Medical Center and extended the contract to the
4 original awardee, Shertech Pharmacy, through a contract modification.
5

6 337. UPPI representatives filed a similar pre-award protest against the
7 SDVOSB set aside on Solicitation No. VA 246-14-Q-0483 to furnish the same
8 radiopharmaceuticals to a Fayetteville VA Medical Center in Fayetteville, VA.
9 The contracting officer in that instance removed the SDVOSB designation and
10 changed the contract to a small business set aside solicitation.
11

12 338. In a third instance, on July 16, 2015, the Comptroller General from
13 the General Accountability Office (GAO) issued a decision in a VA radiopharmacy
14 bid protest filed by a small business radiopharmaceutical business, Triad Isotopes,
15 Inc., finding that the "Rule of Two" was improperly applied when awarding the
16 contract to a SDVOSB.
17

18 339. Specifically, the decision found that "the agency's market research
19 was insufficient to conclude that the agency would likely receive quotations from
20 at least two responsible small business concerns that could meet the requirements
21 in the RFQ at a fair market price, and therefore the agency's decision to restrict the
22 solicitation to small business concerns was unreasonable."
23
24
25
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1 340. In short, the GAO found that there were not two or more SDVOSBs
2 qualified to meet the radiopharmaceutical contract requirements in that region, and
3 thus, it was wrong to restrict competition by triggering the Rule of Two.

4
5 341. In a fourth instance, the VA terminated a contract award to Logmet in
6 New Mexico after Senator Martin Heinrich, on behalf of a UPPI member, raised
7 concerns about Logmet subcontracting the radiopharmaceutical work required in
8 the contract to a large business.

9
10 342. UPPI understood that large business to be Cardinal Health.

11
12 343. In all four of these protests, when UPPI members raised concerns and
13 otherwise explained that the SDVOSBs, who are competing and ultimately
14 awarded these contracts, are unqualified for the contract awards, the VA
15 recognized these concerns as valid and withdrew or terminated the contract
16 awards.

17
18 **F. Federal Trade Commission Previously Sanctioned Cardinal**
19 **Health for a Similar Fraudulent Scheme**

20
21 344. In April 2015, the Federal Trade Commission filed a complaint
22 against Cardinal Health seeking injunctive and other equitable relief, including
23 disgorgement, *see FTC v. Cardinal Health*, Case No. 15-cv-3031 (S.D.N.Y. Apr.
24 20, 2015).

25
26 345. The FTC complaint alleged that Cardinal Health illegally
27 monopolized 25 local markets, including Spokane, Washington, for the sale and
28

1 distribution of radiopharmaceuticals and forced hospitals and clinics to pay inflated
2 prices for the drugs. *See id.*

3
4 346. The FTC complaint explained that from 2003 through 2008, Cardinal
5 Health used a variety of tactics to ensure that the manufacturers would not disburse
6 their radiopharmaceuticals to any new competitors in those markets. *See id.*

7
8 347. The FTC concluded:

9 This conduct allowed Cardinal to maintain and exercise
10 monopoly power in each of the relevant markets. By
11 excluding potential rivals, Cardinal denied its customers
12 the benefits of competition and profited from the
13 monopoly prices it charged for all radiopharmaceuticals,
14 including HPAs, in the relevant markets. Importantly,
there was no efficiency benefit or legitimate business
justification.

15 Statement of the Federal Trade Commission, In the Matter of Cardinal Health, Inc.,
16 FTC File No. 101-0006 (April 17, 2015).

17
18 348. Cardinal Health settled those allegations on or about April 20, 2015
19 for \$26.8 million and was ordered to restore competition in six markets where
20 Cardinal Health remains the dominant radiopharmacy. *See* FTC Press Release,
21 “Cardinal Health Agrees to Pay \$26.8 Million to Settle Charges it Monopolized 25
22 Markets for the Sale of Radiopharmaceuticals to Hospitals and Clinics, April 20,
23 2015, [https://www.ftc.gov/news-events/press-releases/2015/04/cardinal-health-](https://www.ftc.gov/news-events/press-releases/2015/04/cardinal-health-agrees-pay-268-million-settle-charges-it)
24 agrees-pay-268-million-settle-charges-it.
25
26
27
28

1 349. Cardinal Health is continuing to monopolize the radiopharmacy
2 market but behind the cloak and protection of SDVOSBs.
3

4 **G. Materiality: The Wrongdoing Alleged Was Material to The**
5 **Government's Decision to Award the Contracts and Pay the**
6 **Claims**

7 350. The conduct alleged in this Complaint is material as that term is
8 defined under the False Claims Act. The – “term “material” means having a
9 natural tendency to influence, or be capable of influencing, the payment or receipt
10 of money or property” – under the False Claims Act.
11

12 351. The focus of this materiality inquiry is “the effect on the likely or
13 actual behavior of the recipient of the alleged misrepresentation.”
14

15 352. This inquiry can be undertaken from either the perspective of a
16 reasonable person or the particular defendant: a matter is material (1) if a
17 reasonable person would attach importance to it in determining a choice of action
18 in the transaction; or (2) if the defendant knew or had reason to know that the
19 recipient of the representation attaches importance to the specific matter in
20 determining a choice of action, regardless of whether a reasonable person would do
21 so.
22
23

24 353. The defendants presented (or caused to be presented) false claims, or
25 made (or caused to be made) false statements material to a claim, under the False
26 Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, by setting up a sham venture
27
28

1 whereby a billion-dollar company used a front company in order to improperly
2 obtain contracts intended for a SB or SDVOSB-qualified business.

3
4 354. Had the Government known that front company was not performing at
5 least 50 percent of the work under the contract, it would not have awarded these
6 contracts, thus, the materiality standard under the False Claims Act has been met.

7
8 355. No reasonable person would conclude that the Government would not
9 attach importance to a misrepresentation regarding the company's eligibility for
10 contracts expressly and exclusively reserved for SBs and SDVOSBs that perform
11 at least 50 percent of the work under the contract.

12
13 356. To the extent that Government contracting officers were indifferent to
14 the alleged fraud set forth in this Complaint, or stuck their head in the sand, or had
15 actual knowledge or conspired to commit the fraud, they were acting without
16 authority.

17
18 357. Congress made express its intent regarding the materiality of any
19 misrepresentations, as alleged in this Complaint, made by a contractor when
20 bidding on a contract solicitation that was either explicitly a SB or SDVOSB set
21 aside or implicitly intended for a SDVOSB pursuant to the Rule of Two.

22
23 358. Congress mandated that such a contractor "shall be subject to" civil
24 prosecution under the FCA under 15 U.S.C. § 637(m)(5), and as applied expressly
25 to SDVOSBs under 15 U.S.C. § 657f(d) ("Enforcement; penalties").
26
27
28

1 “(C) *Penalties In addition to the penalties described in section*
2 *645(d) of this title [15 U.S.C.], any small business concern that is*
3 *determined by the Administrator to have misrepresented the status of*
4 *that concern as a small business concern owned and controlled by []*
5 *[service-disabled veterans] for purposes of this subsection, shall be*
6 *subject to—*

7 (i) *section 1001 of title 18; and*

8 (ii) *sections 3729 through 3733 of title 31 [the False Claims*
9 *Act].”*

10 359. It is a material misrepresentation under the False Claims Act by the
11 contractor-defendant that it satisfied the 50 percent requirements for federal
12 program contracts because the Government’s money would never have been paid
13 to defendant had the Government’s agents known the 50 percent requirements had
14 been flouted and not met. Such an undisclosed fact was material because no one
15 can say with reason that the Government would have signed this contract if
16 informed of the likelihood of the undisclosed fact. The Government’s money
17 would never have been obligated towards the contracts had its agents known the
18 contractor was not properly qualified or intending to do 50% or more of the work
19 when it bid on the contracts and no one can say with reason that the Government
20 would have entered the contracts if informed of the undisclosed fact that the
21 contractor was not properly qualified or intending to do 50% more of the work.
22
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H. H. Defendants Fraudulently Induced the Government to Award Contracts for Dangerous Radio-Pharmaceutical Products Administered to Patients To Unqualified and Unlicensed "Front Companies."

360. To subvert and defeat Congress' goal to award contracts to qualified small businesses such as Plaintiff's members, Defendants made false statements calculated to further enrich the global large business of Cardinal Health.

361. Cardinal Health, a large global business, orchestrated a scheme to fraudulently induce the award of contracts, based on the false statement that there were at least two or more qualified "SDVOSBs" which were licensed and qualified to handle these dangerous substances. In fact, it was Cardinal Health waiting in the wings to fraudulently obtain the contracts once the "Rule of Two" was invoked.

362. Defendants thus fraudulently induced VA to apply the "Rule of Two," and thus to award the contracts in the name of the unlicensed and unqualified SDVOSBs, rather than to qualified small businesses that could handle these dangerous products safely.

363. In violation of legal requirements ensuring the integrity of small business contracting, Defendants misrepresented and concealed that the "front companies" did little if any of the work. The result was that legitimate, qualified small businesses lost these contracts because of the fraud of Cardinal Health and the other defendants in fraudulently inducing the award of these contracts.

1 364. It is well-established that when a party receives a federal contract as a
2 result of a material misrepresentation, each and every request for payment under
3 such contract constitutes a false claim. *See United States v. Lockheed Martin*
4 *Eng'g & Sci. Servs. Co.*, 491 F.3d 254, 259 (5th Cir. 2007) (noting that, where
5 contract is awarded as a result of false representations, subsequent claims for
6 payment under the contract are “actionable false claims” since “they derived from
7 the original fraudulent misrepresentation”), *citing Marcus v. Hess*, 317 U.S.537,
8 543-544 (1943); *United States v. Univ. of Phoenix*, 461 F.3d 1166, 1170-1171 (9th
9 Cir. 2006) (“[E]ach and every claim submitted under a contract ... which was
10 originally obtained by means of false statements or other corrupt or fraudulent
11 conduct ... constitutes a false claim”), *quoting* S. Rep. No. 99-345, at 9 (1986),
12 reprinted in 1986 U.S.C.C.A.N. 5266, 5274; *United States ex rel. Wilson v.*
13 *Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) (“the term ‘false or
14 fraudulent claim’ includes those instances ‘when the contract or extension of
15 government benefit was obtained originally through false statements or fraudulent
16 conduct’”); *see also United States ex rel. Longhi v. United States*, 575 F.3d at 473
17 (5th Cir. 2009) (holding that entire contract amount was proper measure of
18 damages on fraudulently induced contract).

19
20
21
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25 365. This case is similar to another case pending in this District, which the
26 Court allowed to proceed after denying a motion to dismiss (and later partial
27 summary judgment on damages). *U.S. ex. Rel. Savage, Savage Logistics, LLC v.*
28

1 *Washington Closure Hanford LLC, et al.* (E.D.W.A.) (Oct. 6, 2015) (Order Ruling
2 on Pending Dismissal Motions And Other Motions, And Amending The Case
3 Caption), Judge Salvador Mendoza.

4
5 366. The court said in an Order denying a motion to dismiss: The old
6 proverb, "It's not what you know but who you know," is at the heart of the
7 assertions brought by the United States' and the Relators Salina Savage and her
8 business Savage Logistics. The Plaintiffs allege that Defendants took their personal
9 connections a step too far in order to gain a financial benefit, i.e., Defendants
10 reached agreement amongst themselves to establish a façade of small,
11 disadvantaged businesses that applied for, and were awarded small business
12 government contracts by the prime contractor while the work under the contracts
13 was actually performed by a large business rather than the small business.
14
15
16

17 **IV. DAMAGES AND PENALTIES**

18 **A. The Wrongdoing Alleged Harmed The Programs Designed to** 19 **Help Qualified Small Businesses, Including Qualified SDVOSBs**

20
21 367. As set forth above, the Federal Government has continuously
22 supported giving preferred status to SDVOSBs in Government contracting, and has
23 implemented, through executive orders, strategies to achieve the goal of honoring
24 the extraordinary service that United States veterans have provided this nation.
25 Executive Order No. 13360 (Oct. 21, 2004).
26
27
28

1 **1. Damages**

2 368. Defendants are jointly and severally liable for civil penalties
3
4 consistent with the False Claims Act and other provisions, plus three times the
5 amount of the damages which the Government sustained as a result of the
6 violations. 31 U.S.C. § 3729(a)(1).
7

8 369. The legislative history of the FCA evidences Congress's intent to
9 leave the courts "free to fashion measures of damages on a case by case basis." S.
10 Rep No. 615, 96th Cong., 2d Sess, at 4.
11

12 370. There are numerous ways to measure damages in cases such as this
13 where the government contracts for and receives a tangible asset (nuclear
14 pharmaceutical services), but fails to achieve the contracted for programmatic
15 goal—the economic benefit to businesses that qualify as service-disabled and
16 veteran-owned.
17

18 371. As set forth in this Complaint, Congress set out to empower veterans
19 through entrepreneurship. That noble goal has been knowingly undermined by
20 defendants.
21

22 372. One appropriate measure of damages is the full amount paid to
23 defendants under the contract. When a contractor violates a pre-condition of
24 payment that relates directly to a contractor's eligibility to supply a particular good
25 or service, nothing is due to the contractor, regardless of whether goods or services
26
27
28

1 were provided, and the resulting measure of damages to the United States is the
2 full value of any amount paid out by the government.

3
4 373. This theory of damages is supported by the “presumed-loss rule.” In
5 September 2010, Congress enacted the “presumed-loss rule,” which provides that
6 damages are presumed to be the full amount expended on a contract obtained as a
7 result of willful misrepresentation of small business size status. Congress created
8 the rule precisely for cases like this one.

9
10 374. The Small Business Jobs Act of 2010 (H.R. 5297) (SBJA) was
11 enacted on September 27, 2010. It created a program fund designed to increase the
12 availability of credit for small businesses. Under the law, Congress created the
13 “presumed-loss rule” (15 U.S.C. § 632(w)(1), which provides that:
14
15

16 In every contract [or] subcontract ... which is set aside,
17 reserved, or otherwise classified as intended for award to
18 small business concerns, there shall be a presumption of
19 loss to the United States based on the total amount
20 expended on the contract [or] subcontract ...whenever it
21 is established that a business concern other than a small
22 business concern willfully sought and received the award
23 by misrepresentation.

24 375. Under another alternative theory of damages, damages are arguably at
25 least 50 percent of the total value of the contract because SBA regulations
26 mandated that Caring Hands and Logmet perform at least 50 percent of the value
27 of the work. 13 C.F.R. § 125.6(a)(1) – (a)(2).
28

1 376. A decision on summary judgment in the *Washington Closure Hanford*
2 case may be instructive on calculating damages. The Court made the following
3 findings (below). *U.S. ex. Rel. Savage, Savage Logistics, LLC v. Washington*
4 *Closure Hanford LLC, et al.* (E.D.W.A.) (Aug. 24, 2017) (Order denying Motion
5 for Partial Summary Judgement on Damages), Judge Salvador Mendoza.
6

7
8 Defendant WCH moves for partial summary judgment on
9 one issue only—the permissible scope of the
10 Government’s damages for WCH’s alleged violations.
11 WCH argues principally that the Government’s damages
12 must be limited to the remedies provided by the RCC
13 contract. WCH alternatively argues that, if the contract
14 remedies are not exclusive, the Small Business Act’s
presumption of loss does not apply and the value the
Government received by WCH’s and the subcontractors’
performance must offset any damages.

15 Each of WCH’s arguments fail. First, the RCC Contract
16 remedies are not exclusive in this case. The RCC
17 Contract provides remedies for failure to meet SBS goals
18 and to make a good faith effort to comply with the SBS
19 plan, but those remedies do not address, and do not
20 adequately compensate the Government for, alleged
21 willful misrepresentation of the small-business or
22 women-owned-business status of certain subcontractors.
23 Second, the Small Business Act’s presumption of loss
24 applies to the Government’s claims against WCH.
25 Finally, because the harm caused by falsely claiming that
26 a subcontractor is a qualifying small business is the lost
27 value of business and experience going to a qualifying
28 small business, the value of the work performed under
the contract is irrelevant and cannot offset the damages
for that alleged harm. There is no simple formula for
calculating “actual damages” in this context. In apparent
recognition of this difficulty, Congress established a
presumption of loss that sets the baseline for the

1 Government's damages in cases like this one, citing 15
2 U.S.C. § 632(w)(1).

3 **B. The Whistleblower Is a Proper Relator and Entitled to A Share**

4 **1. No Public Disclosure/Original Source**

5
6 377. Relator has standing to bring this action pursuant to 31 U.S.C.
7 §3730(b)(1). Prior to becoming aware of any known public disclosure under
8 subsection (e)(4)(a) of 31 U.S.C. § 3730, Relator voluntarily disclosed to the
9 Government the information on which the allegations or transactions in this claim
10 are based; and Relator has knowledge that is independent of and materially adds to
11 any publicly disclosed allegations or transactions that may exist, and has
12 voluntarily provided the information to the Government before filing an action.
13
14

15 **2. Relator Share**

16
17 378. Relator is either entitled to between 15-25 percent of the proceeds that
18 result from this action or any settlement of the claims raised or identified herein,
19 under 31 U.S.C. § 3730(d)(1); or between 25 – 35 percent of the proceeds pursuant
20 to 31 U.S.C. §3730(d)(2).
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1 **V. COUNTS OF COMPLAINT**

2 **COUNT I**

3 **Federal False Claims Act:**

4 **31 U.S.C. § 3729(a)(1)(A)**

5
6 379. The allegations in the preceding paragraphs are incorporated by
7 reference.

8
9 380. Defendants knowingly presented or caused to be presented numerous
10 false or fraudulent claims for payment or approval in violation of 31 U.S.C. §
11 3729(a)(1)(A).

12
13 381. By virtue of these false or fraudulent claims, Defendants are jointly
14 and severally liable to the United States for incurred damages resulting from such
15 false claims, trebled, plus civil penalties for each violation of the Act.

16
17 382. As a result of Defendants' violations, the United States has suffered
18 damages in an amount to be determined at trial.

19 **COUNT II**

20 **Federal False Claims Act:**

21 **31 U.S.C. § 3729(a)(1)(B)**

22
23
24 383. The allegations in the preceding paragraphs are incorporated by
25 reference.

1 384. Defendants knowingly made, used, or caused to be made or used false
2 records or statements material to false or fraudulent claims, in violation of 31
3 U.S.C. § 3729(a)(1)(B).
4

5 385. By virtue of these false or fraudulent claims, Defendants are jointly
6 and severally liable to the United States for incurred damages resulting from such
7 false claims, trebled, plus civil penalties for each violation of the Act.
8

9 386. As a result of Defendants' violations, the United States has suffered
10 damages in an amount to be determined at trial.
11

12 **COUNT III**

13 **Federal False Claims Act:**

14 **31 U.S.C. § 3729(a)(1)(C)**
15

16 387. The allegations in the preceding paragraphs are incorporated by
17 reference.
18

19 388. Defendants knowingly conspired to commit a violation of
20 subparagraph (A), (B), (D), (E), (F), or (G), in violation of 31 U.S.C. §
21 3729(a)(1)(C).
22

23 389. By virtue of these false or fraudulent claims, Defendants are jointly
24 and severally
25

26 liable to the United States for incurred damages resulting from such false
27 claims, trebled, plus civil penalties for each violation of the Act.
28

COUNT V

**Federal False Claims Based on Anti-Kickback Statute
31 U.S.C. § 3729(a)(1)(A); 42 U.S.C. § 1320a-7b(b)**

395. The allegations in the preceding paragraphs are incorporated by reference.

396. Defendants knowingly presented or caused to be presented numerous false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729 (a)(1)(A).

397. The claims were false or fraudulent because they were tainted by kickbacks that Defendants knowingly and willfully provided to referring health care entities and providers and further to physicians who contracted with Defendants to induce referrals for behavioral health services for federal health care program beneficiaries, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

398. By virtue of these false or fraudulent claims, Defendants are jointly and severally liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

399. As a result of Defendants' violations, the United States has suffered damages in an amount to be determined at trial.

COUNT VI

**Federal False Claims Based on Anti-Kickback Statute
31 U.S.C. § 3729(a)(1)(B); 42 U.S.C. § 1320a-7b(b)**

400. The allegations in the preceding paragraphs are incorporated by reference.

401. Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

402. The false records or statements included those appearing on Medicare and Medicaid Provider Agreements and claims submission forms —where Defendants falsely certified to the United States, *inter alia*, that their claims for Medicare and Medicaid payment were true, accurate, and complete—and where Defendants falsely certified to the United States, *inter alia*, their compliance with all “Medicare laws, regulations and program instructions . . . including, but not limited to, the Federal anti-kickback statute.”

403. The false records or statements were material to Defendants’ claims for Medicare payment because Medicare would not have paid the claims absent the records or statements.

404. By virtue of these false or fraudulent claims, Defendants are jointly and severally liable to the United States for incurred damages resulting from such false claims, trebled, plus civil penalties for each violation of the Act.

1 405. As a result of Defendants' violations, the United States has suffered
2 damages in an amount to be determined at trial.

3
4 406. Based on the foregoing, the Government has suffered damages, to be
5 determined at trial, as a result.

6 WHEREFORE, Relator requests that judgment be entered in Plaintiff's
7 favor against Defendants as follows:

8
9 (a) Pursuant to Counts One through Five, for treble the amount of
10 damages incurred by the Government, in an amount to be determined at trial, and
11 penalty of \$11,000 for each false claim submitted or caused to be submitted, each
12 record or statement made, used, presented or caused to be made, by Defendants;

13
14 (b) Awarding Relator its relator's share pursuant to 31 U.S.C. §
15 3730(d)(1) or (2);

16
17 (c) Awarding Relator costs and attorneys' fees pursuant to 31 U.S.C. §
18 3730; and

19
20 (d) Awarding such other relief as is appropriate under the law.

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VI. JURY DEMAND

Plaintiffs hereby request a jury trial in this matter.

DATED this 14th day of November, 2017.

BESTLAW PLLC

By: 

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